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(54) **GUIDEWIRE AND CATHETER LOCKING DEVICE AND METHOD**

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(52) **U.S. Cl.** ..... **604/165.02**; 604/538

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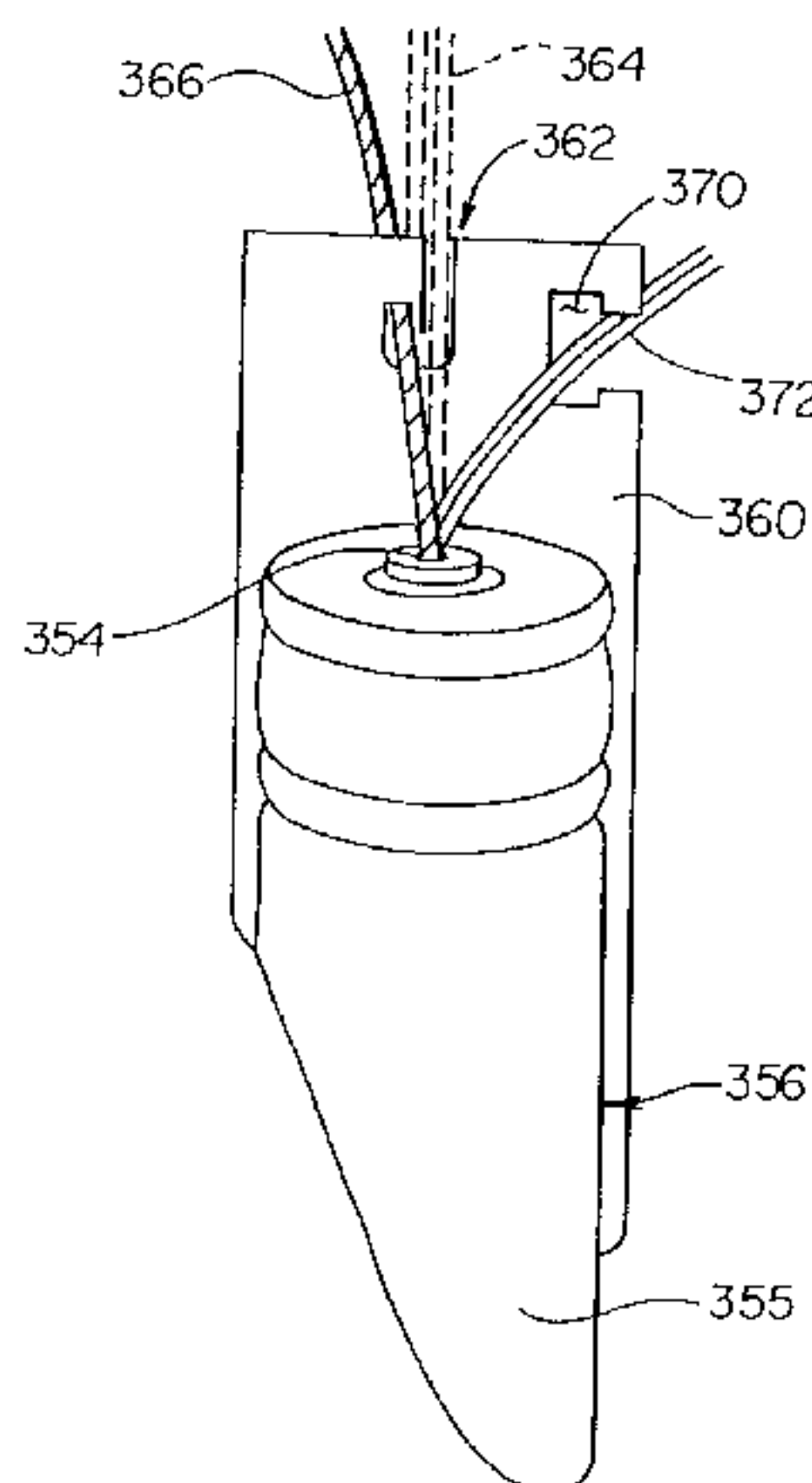
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(57) **ABSTRACT**

Locking device that is mounted on an endoscope or the like for selectively securing the position of a guide wire and/or catheter relative to the endoscope or the like. The locking device preferably includes a side wall with an opening therein for receiving the proximal end of a guide wire or catheter. The opening is preferably J-shaped or boot shaped, and has an entry end and a locking end. Once a guide wire or catheter is in a desired position within a body cavity, the portion of the guide wire or catheter that extends outside of the endoscope or the like may be moved into the opening. More particularly, a portion of the guide wire or catheter may be inserted by an operator through the entry end of the opening and into the locking end, wherein the locking end frictionally secures the position of the guide wire or catheter relative to the endoscope or the like.

**8 Claims, 15 Drawing Sheets**



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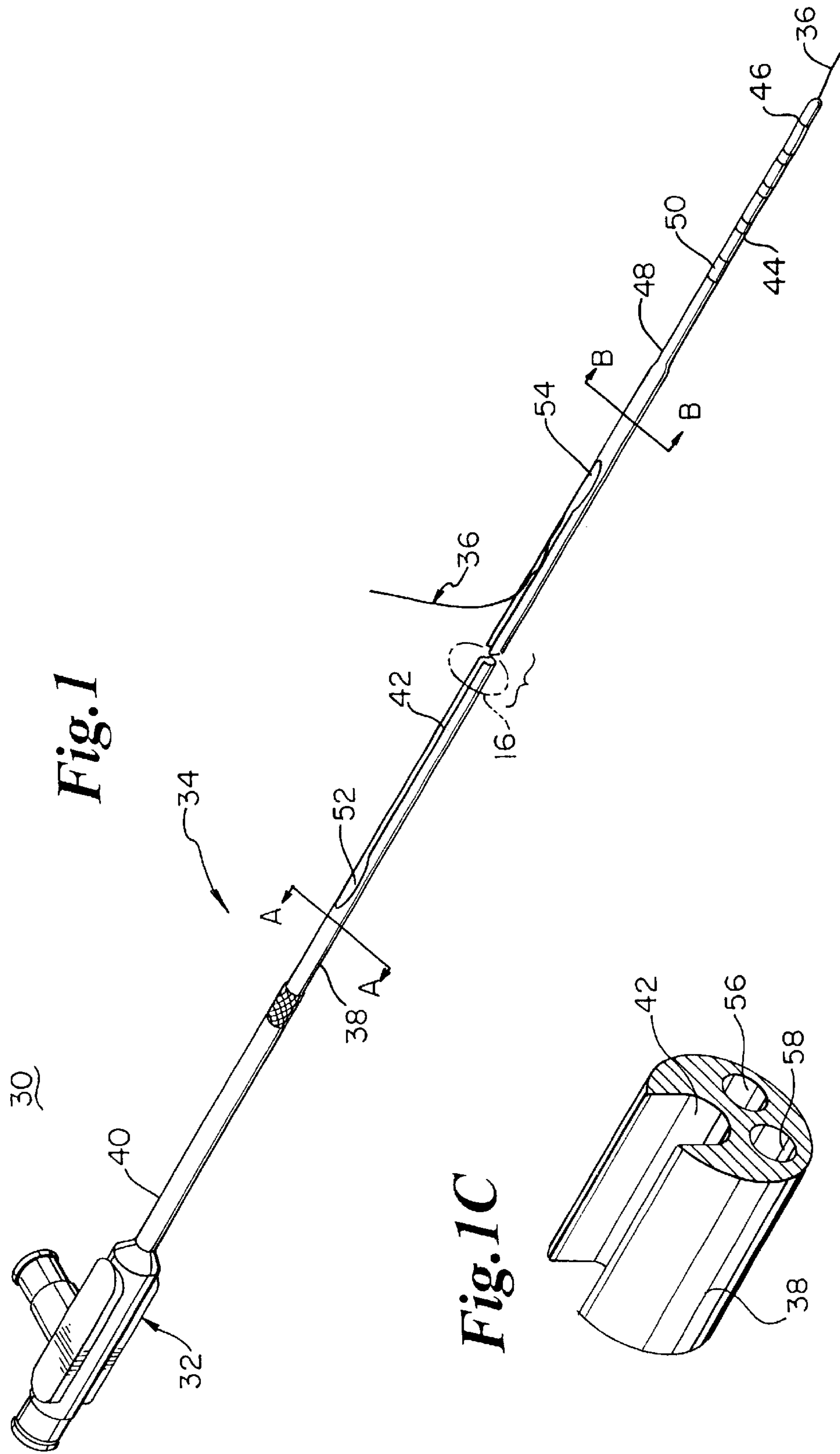
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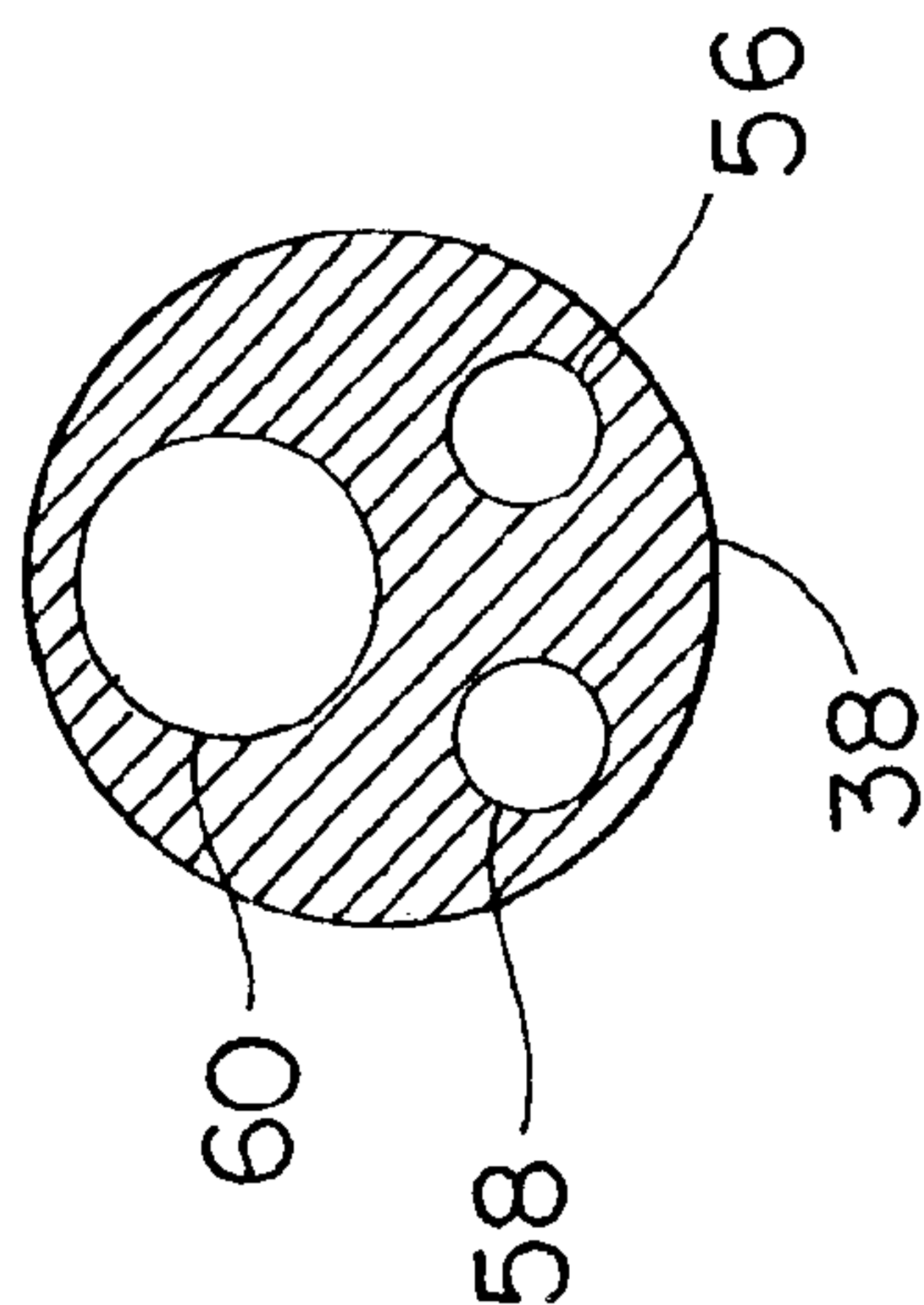




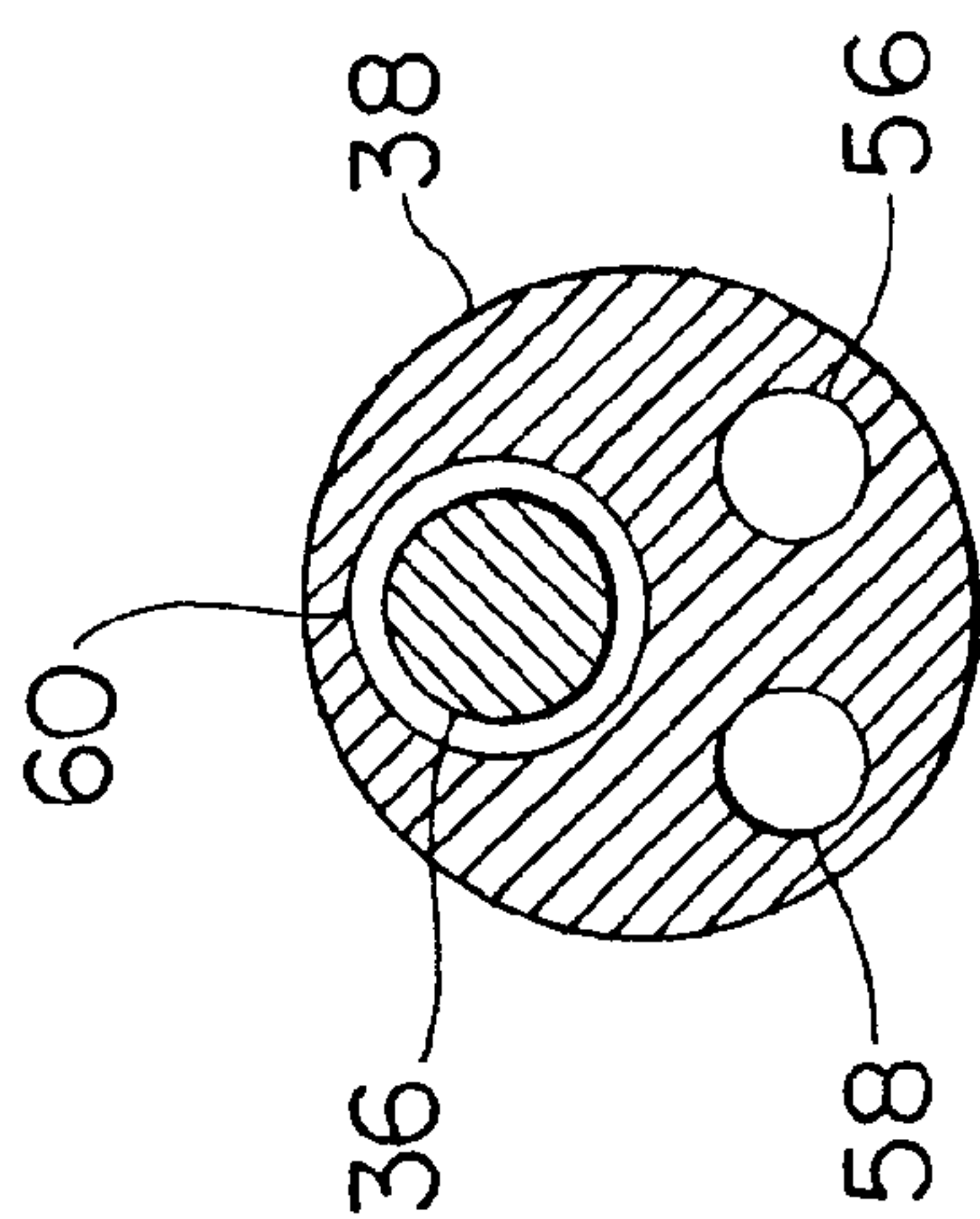
**Fig. 1**

**Fig. 1C**

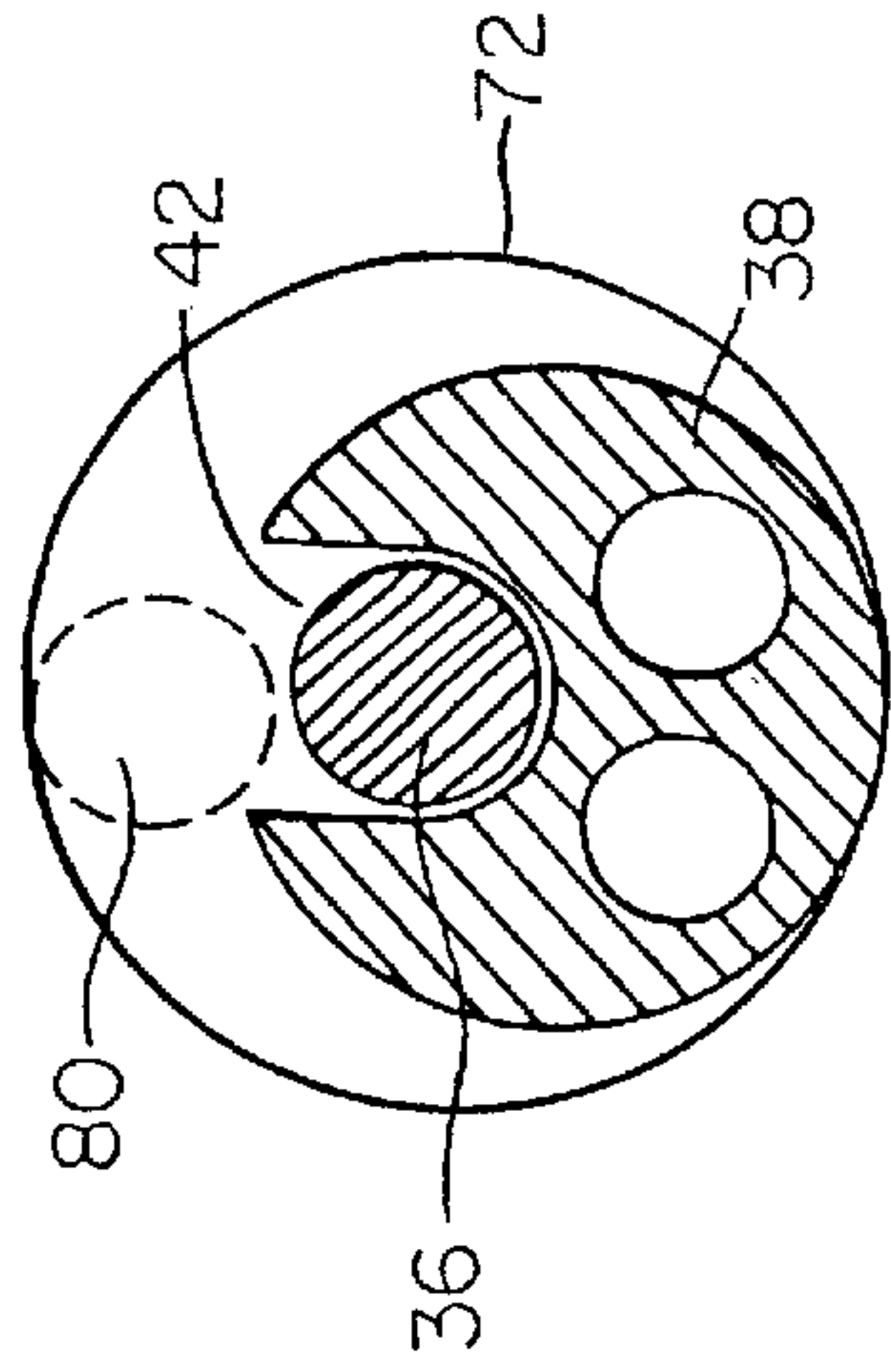
**Fig. 1A**



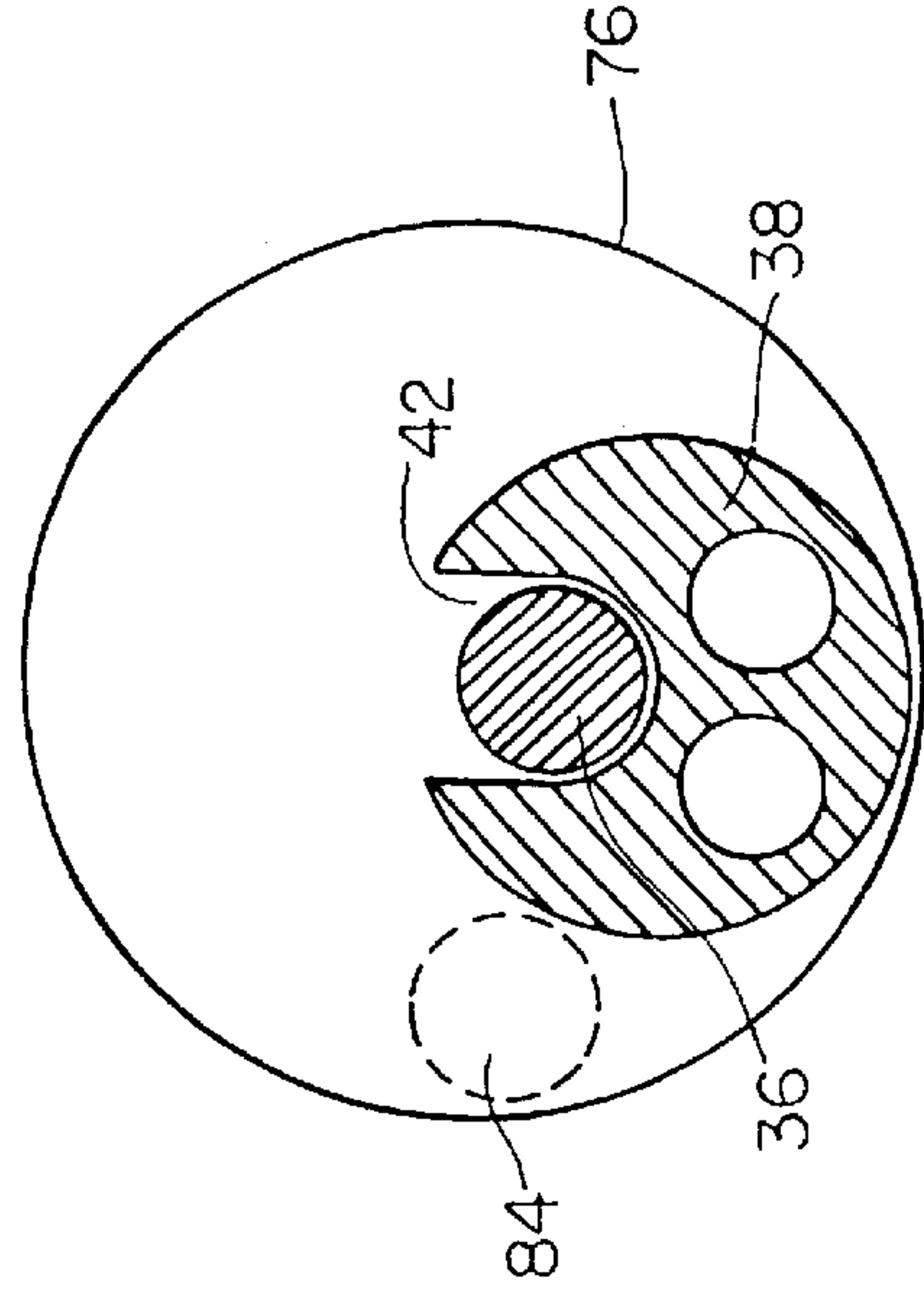
**Fig. 1B**



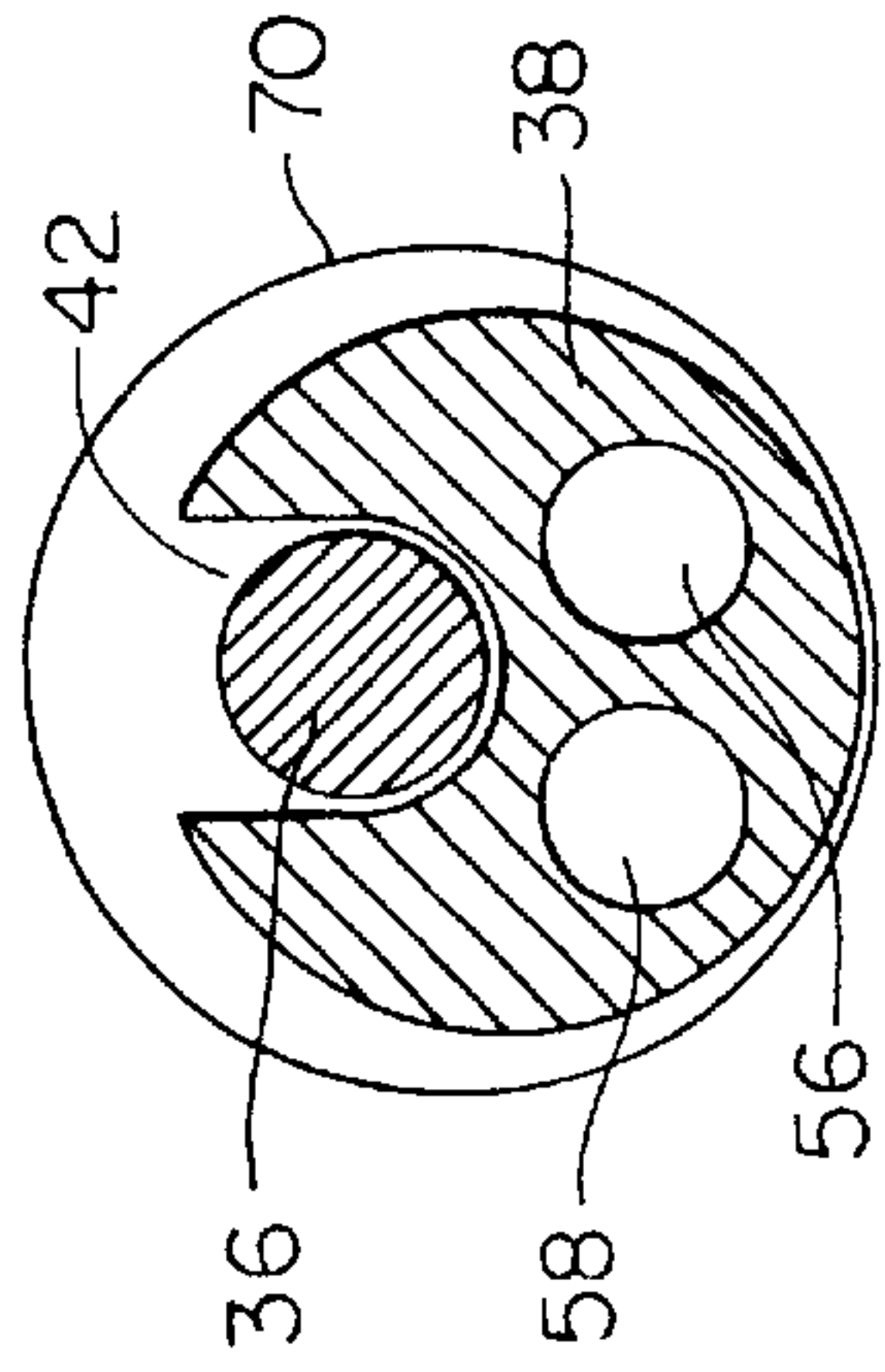
**Fig. 2B**



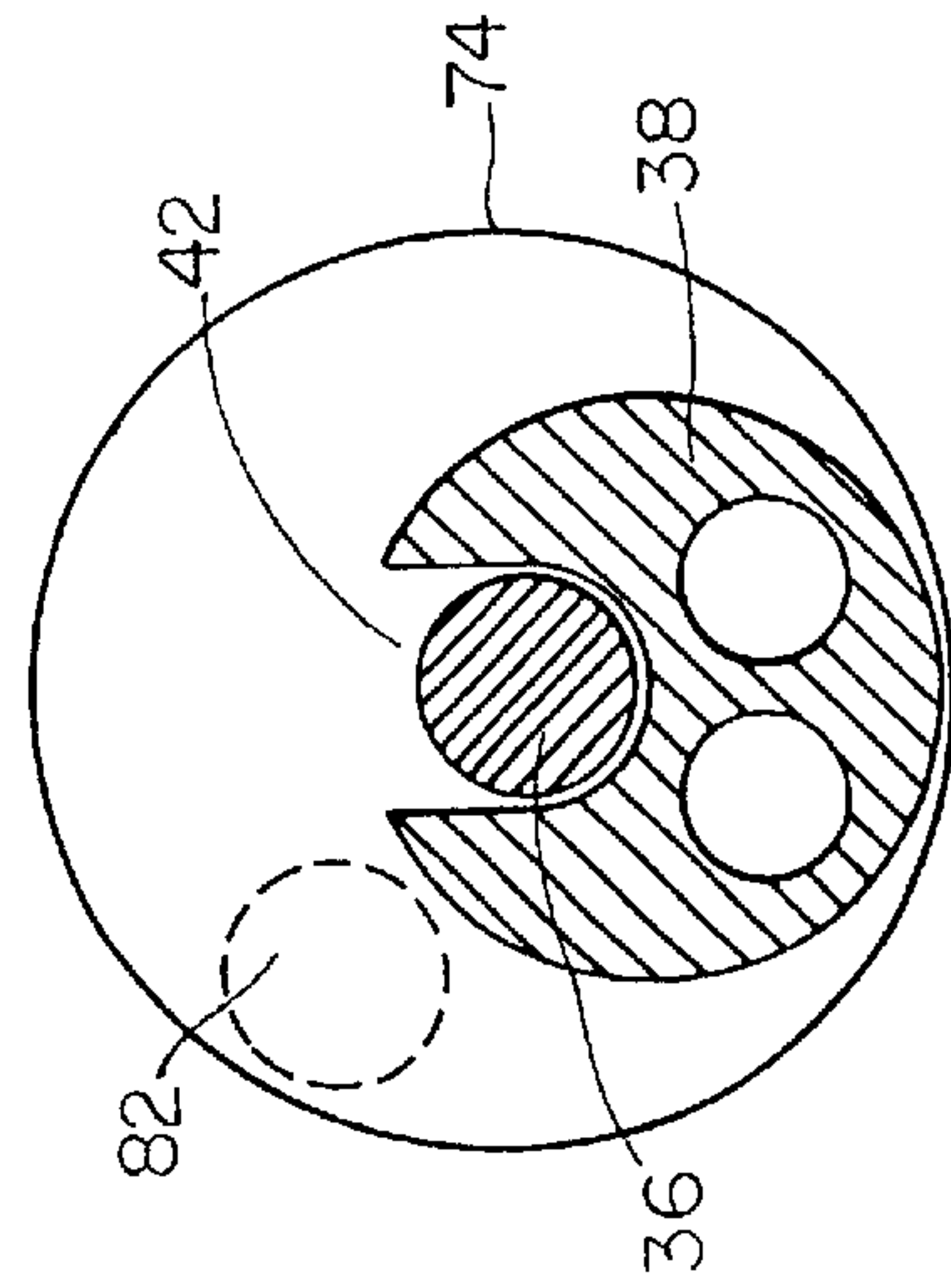
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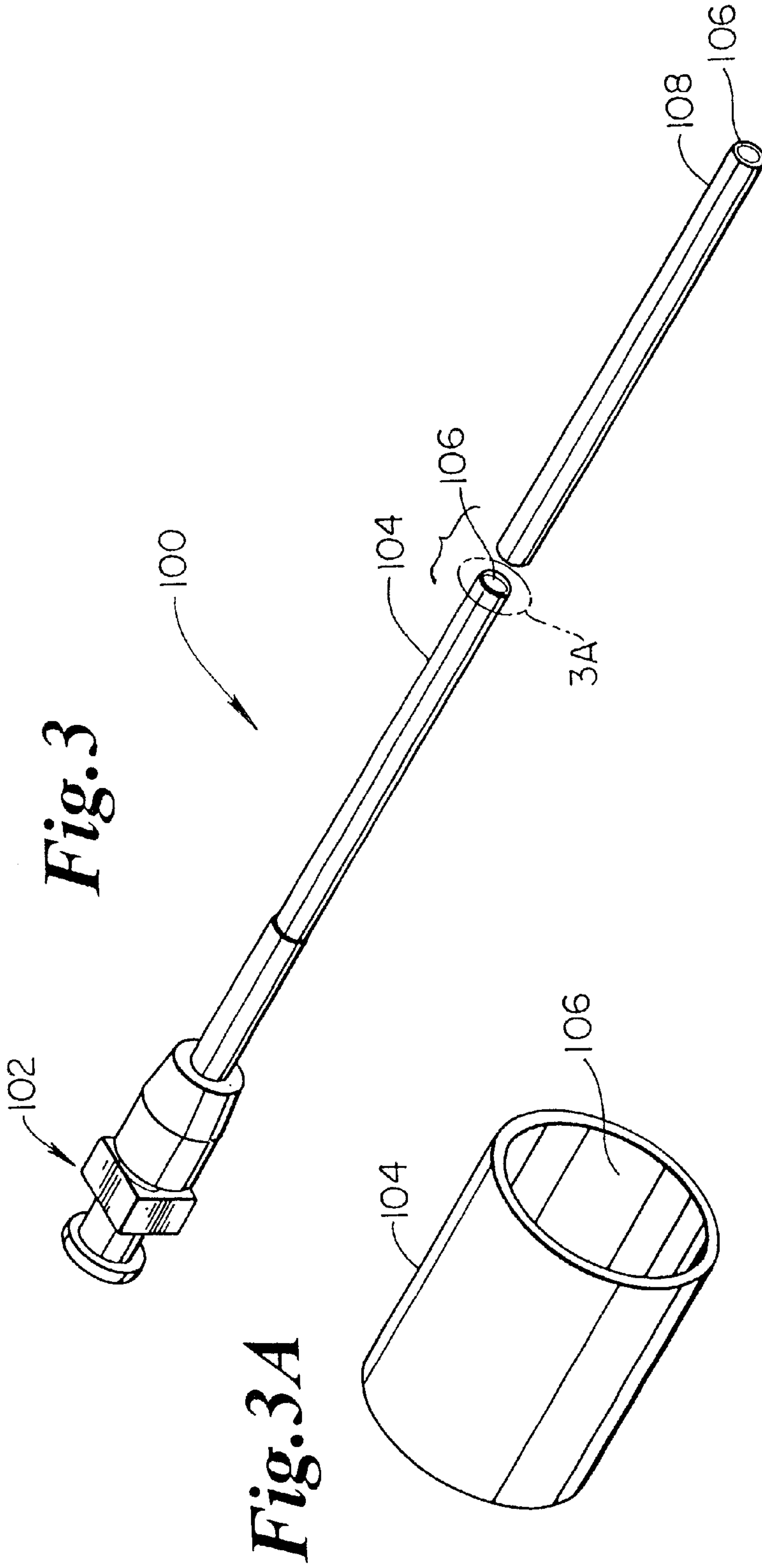


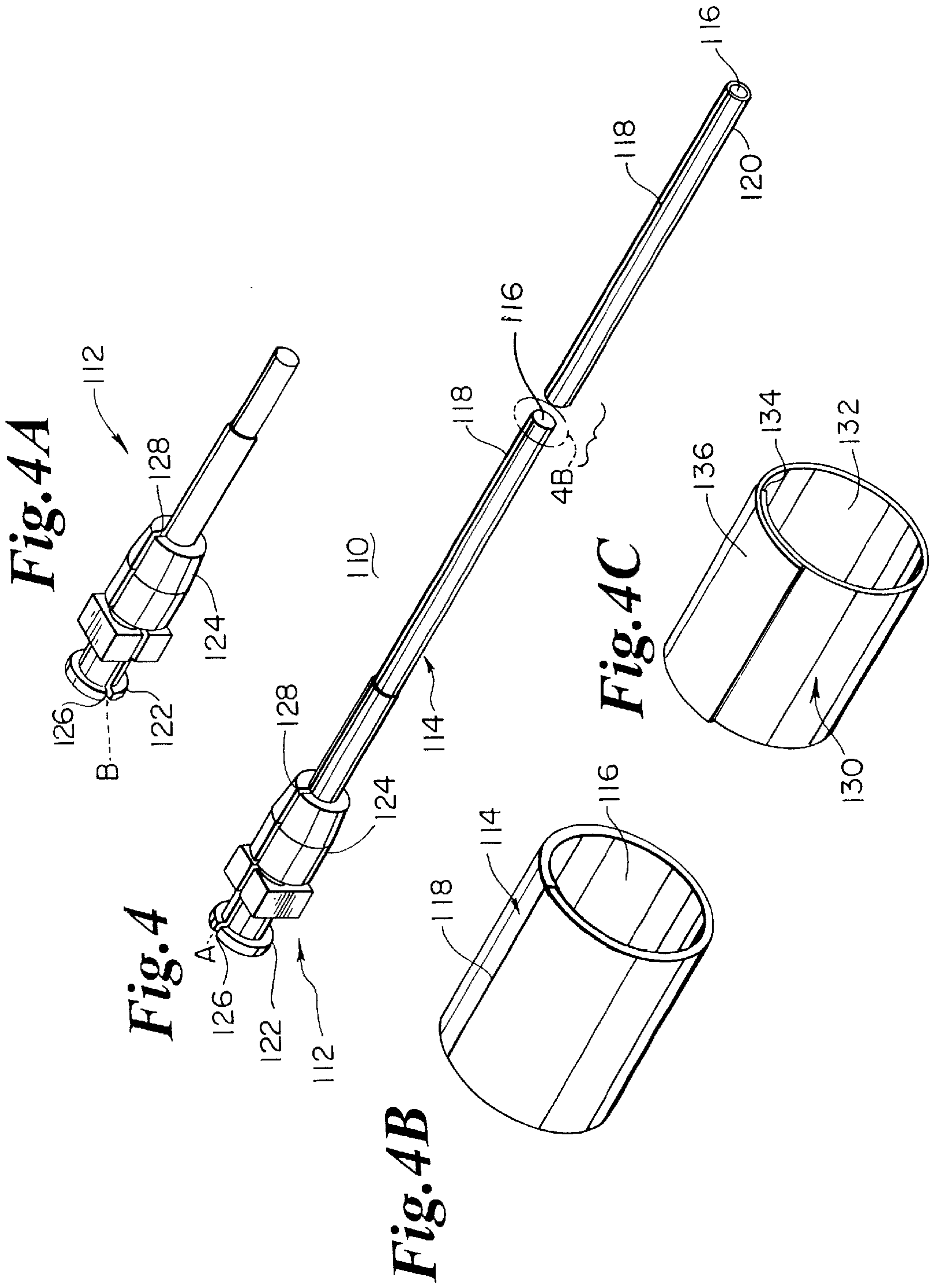
**Fig. 2A**

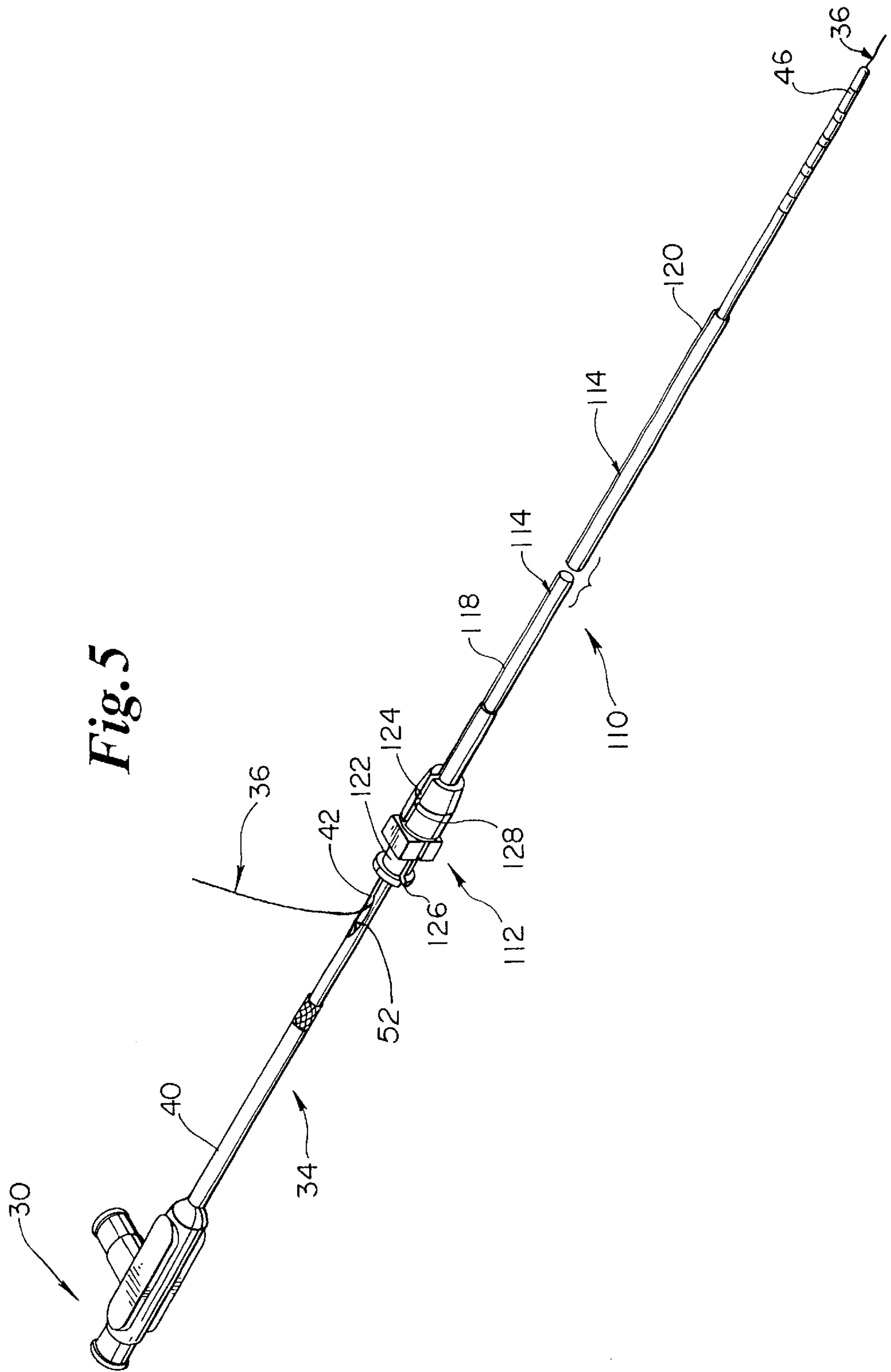


**Fig. 2C**



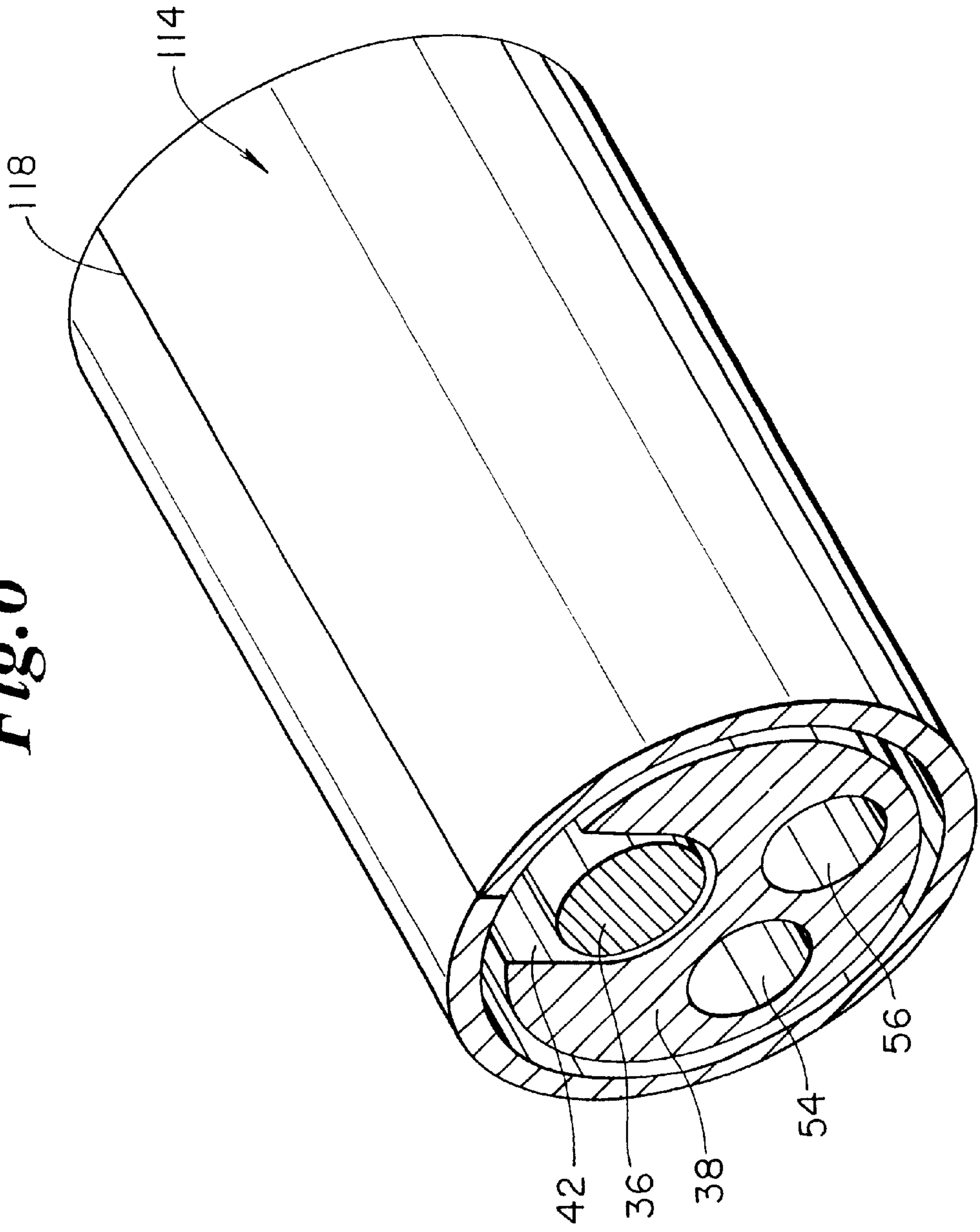


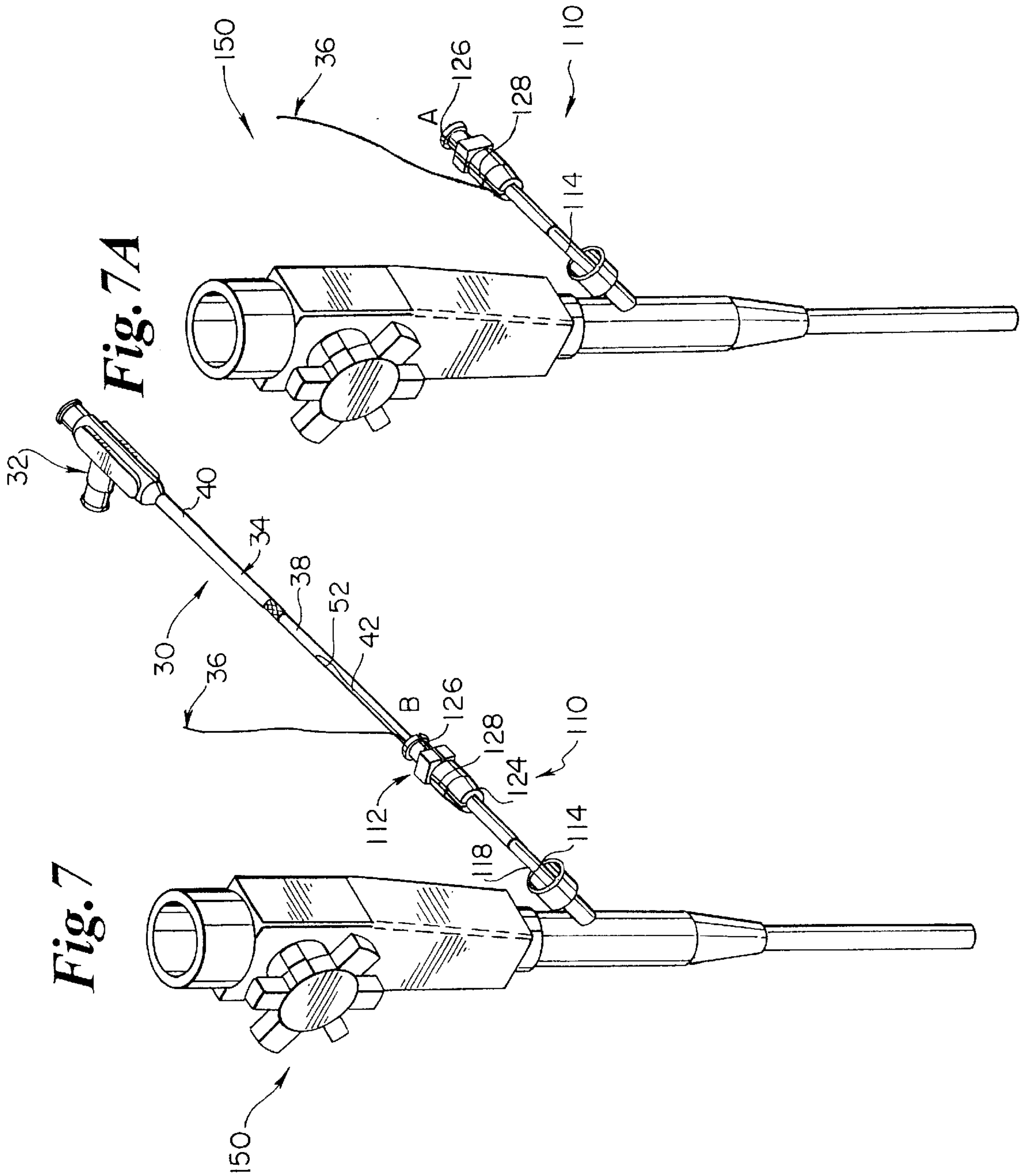


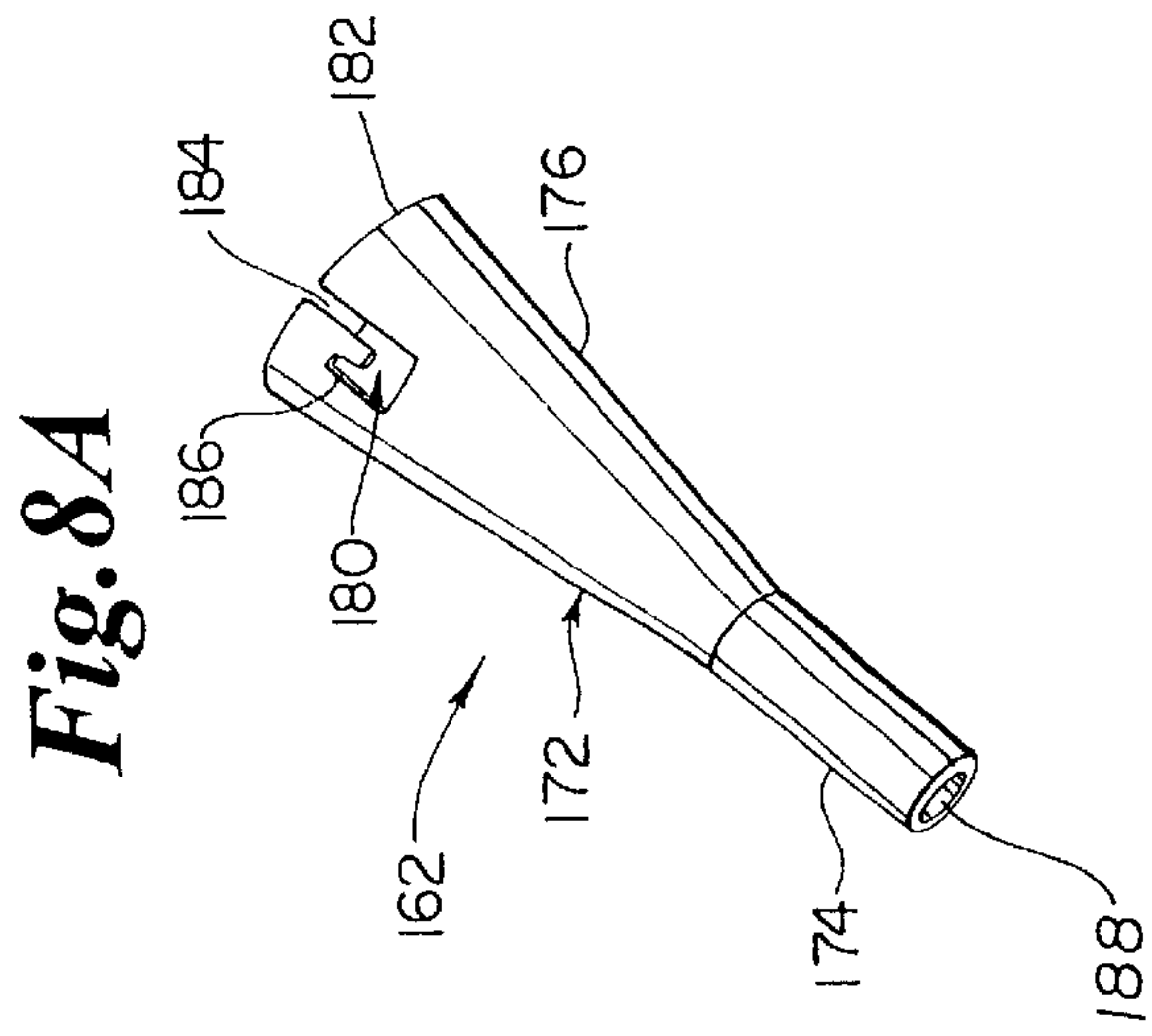
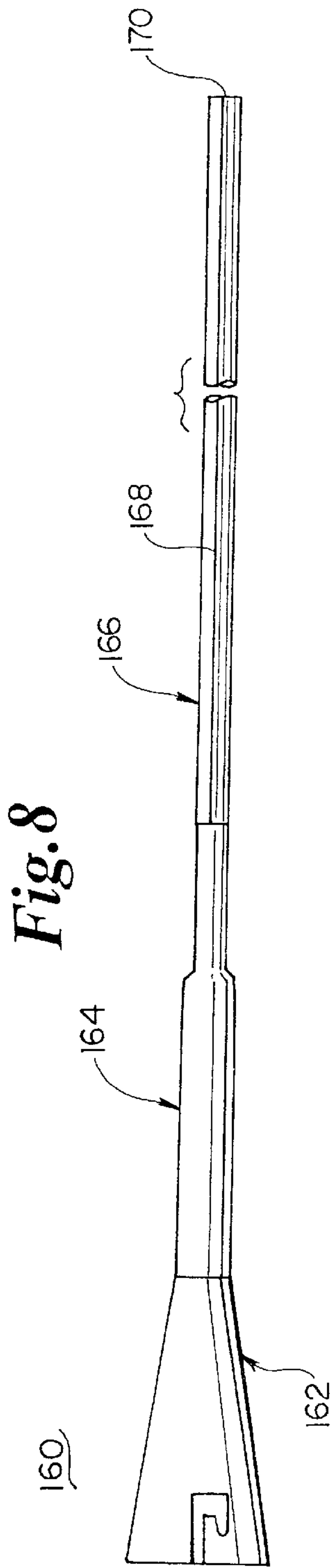


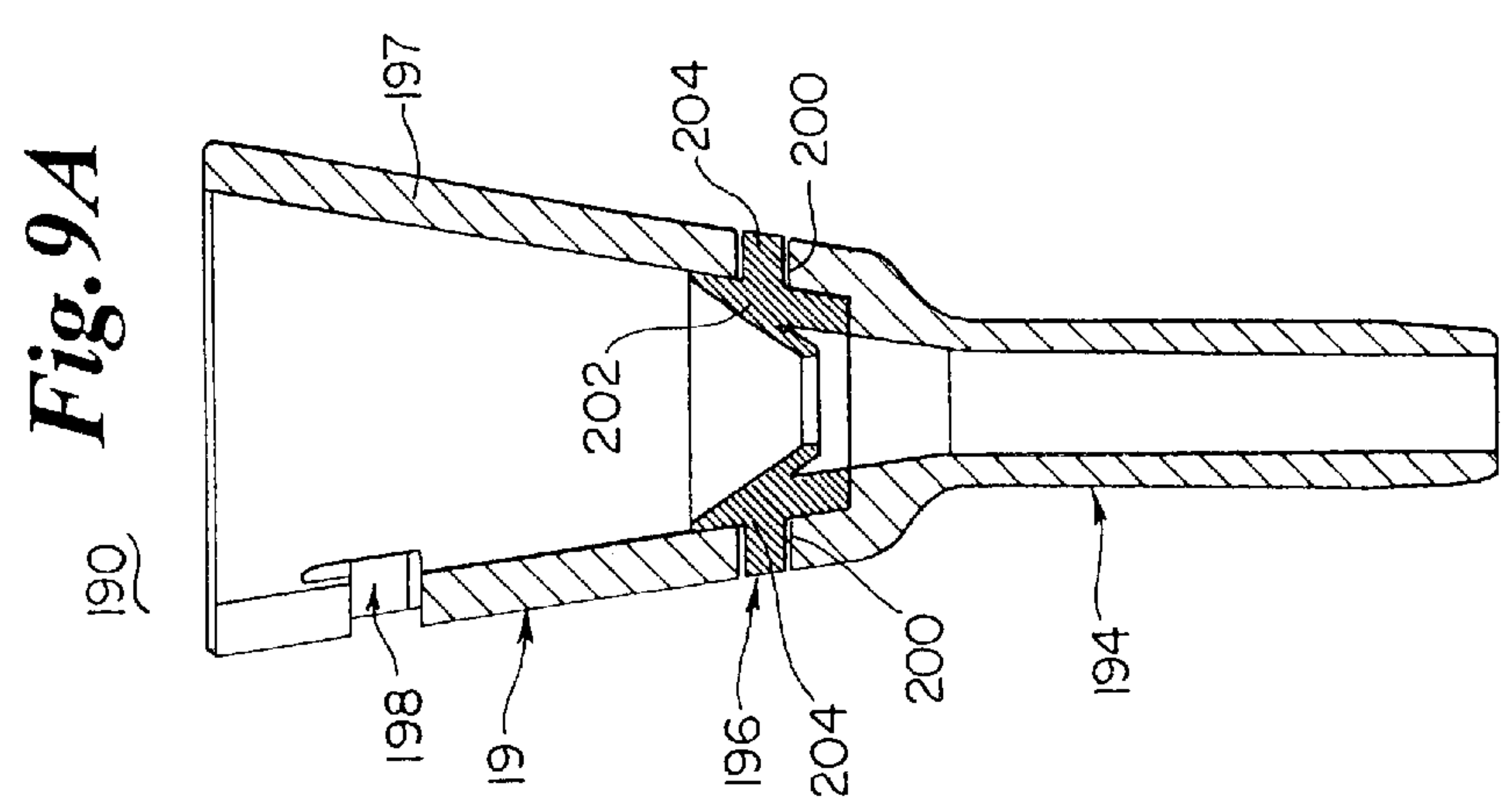
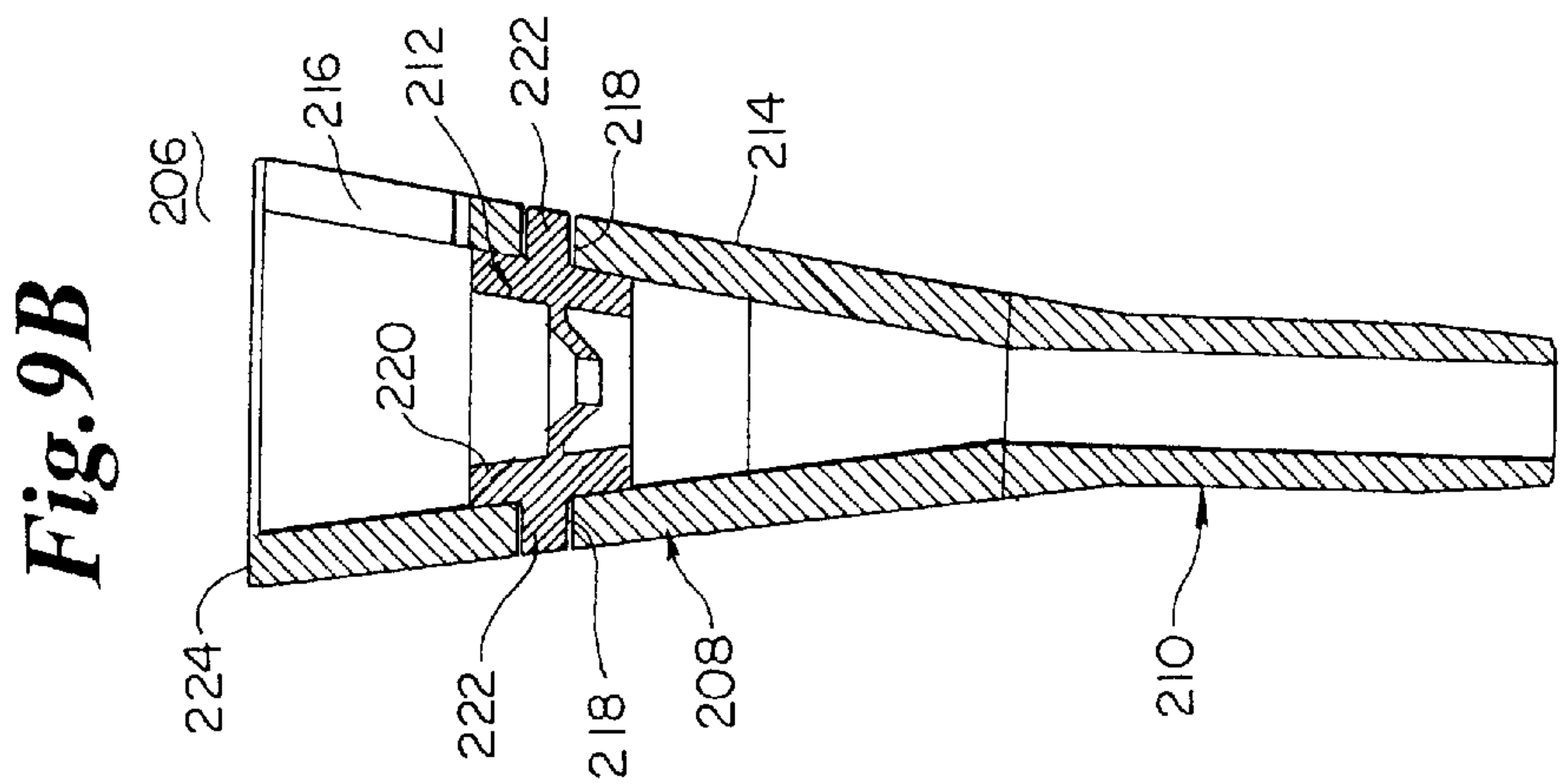
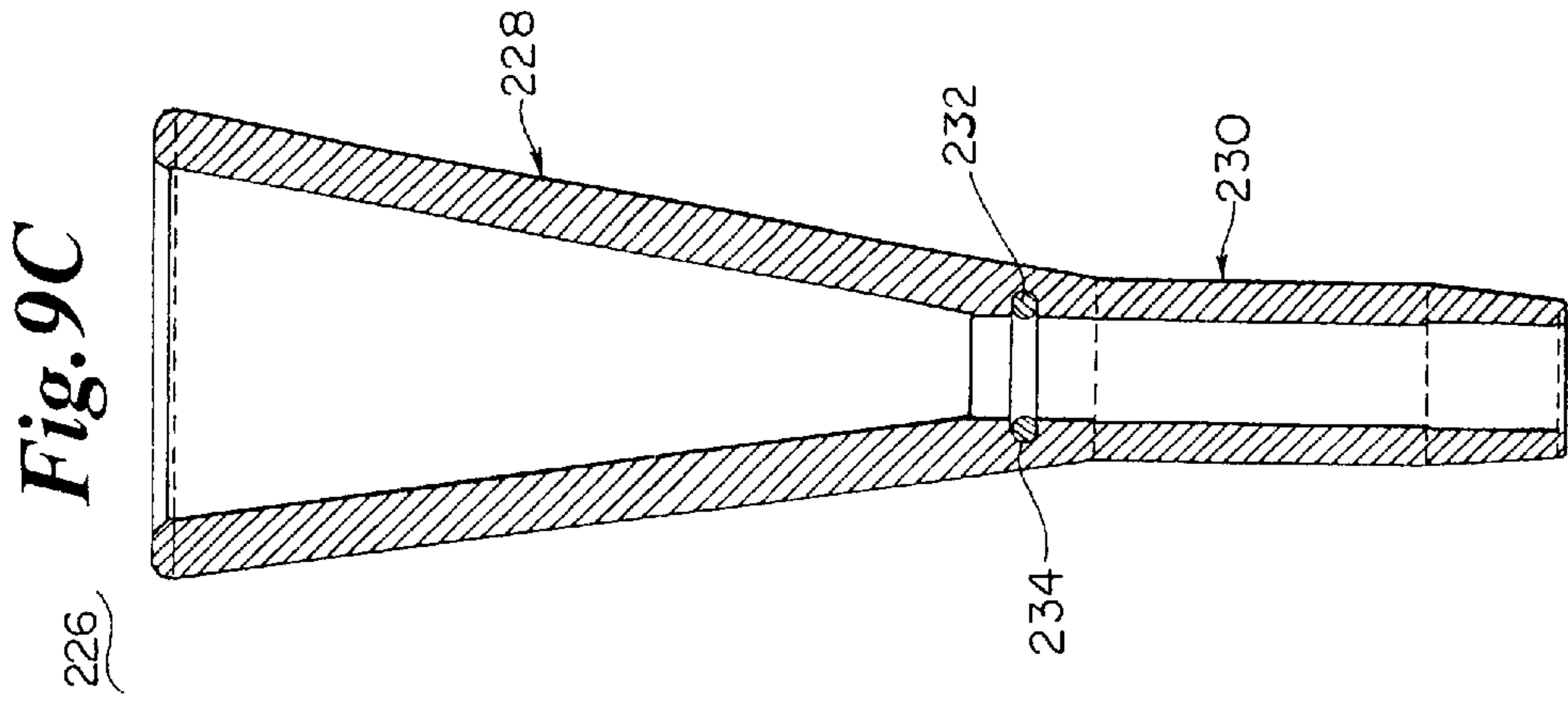


**Fig. 6**



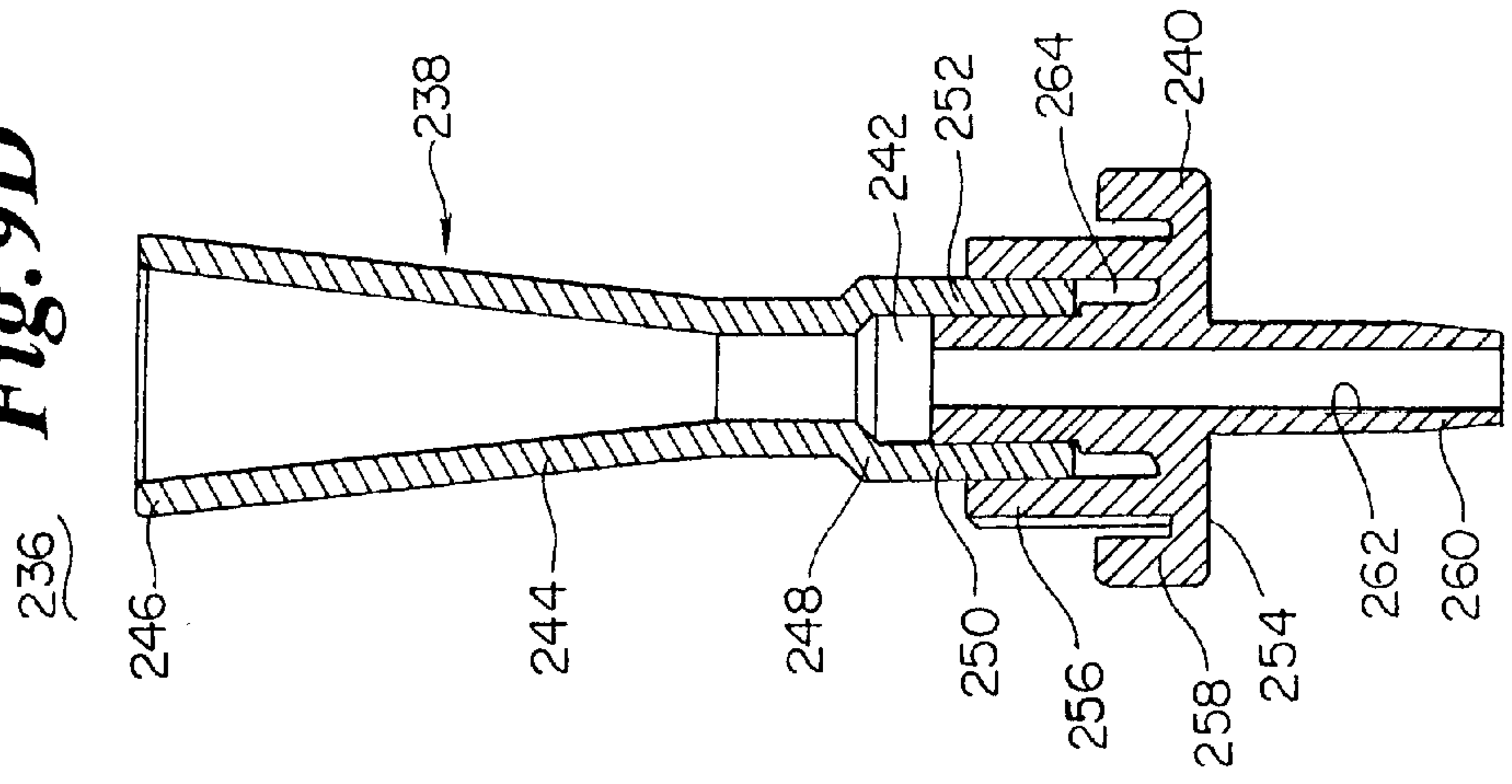




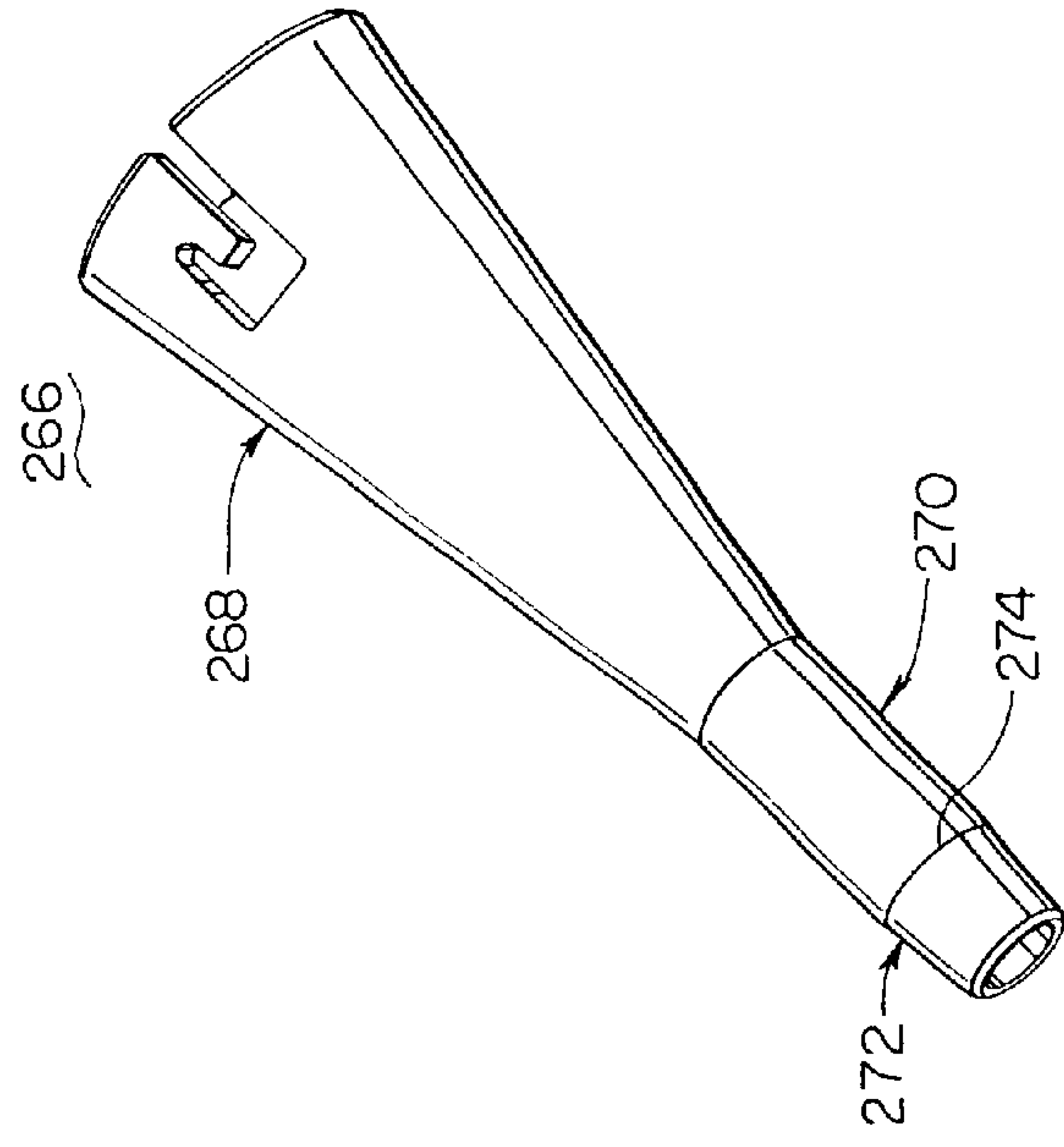




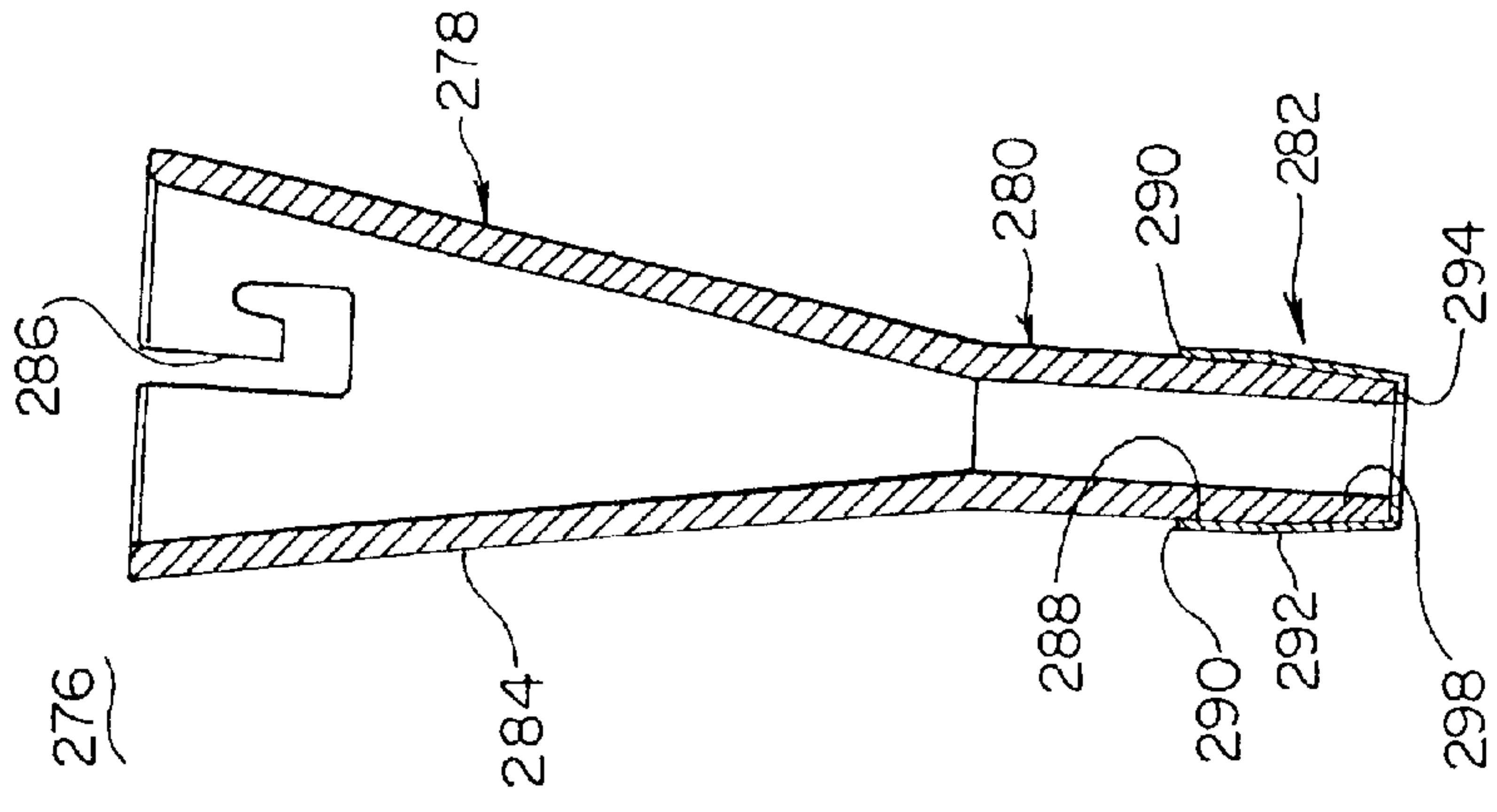
**Fig. 9D**

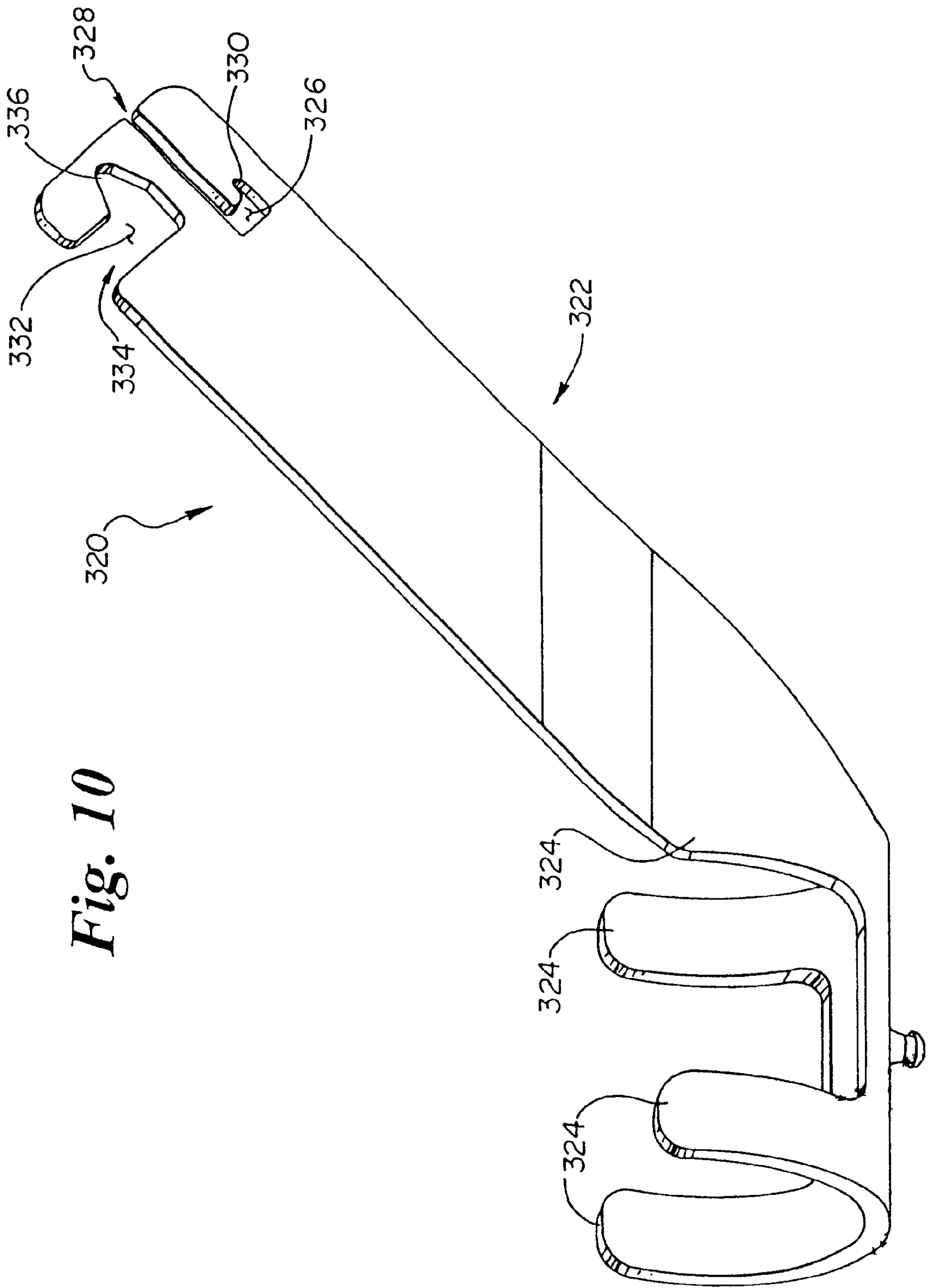


**Fig. 9E**



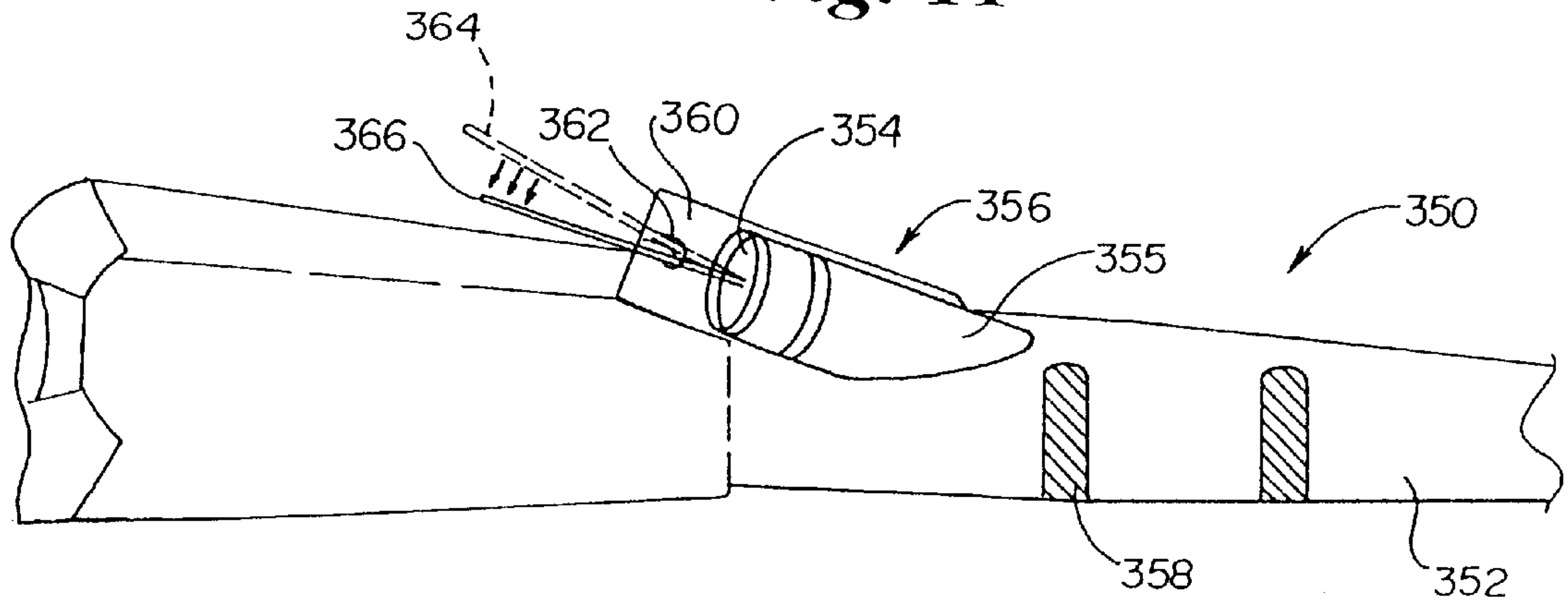
**Fig. 9F**



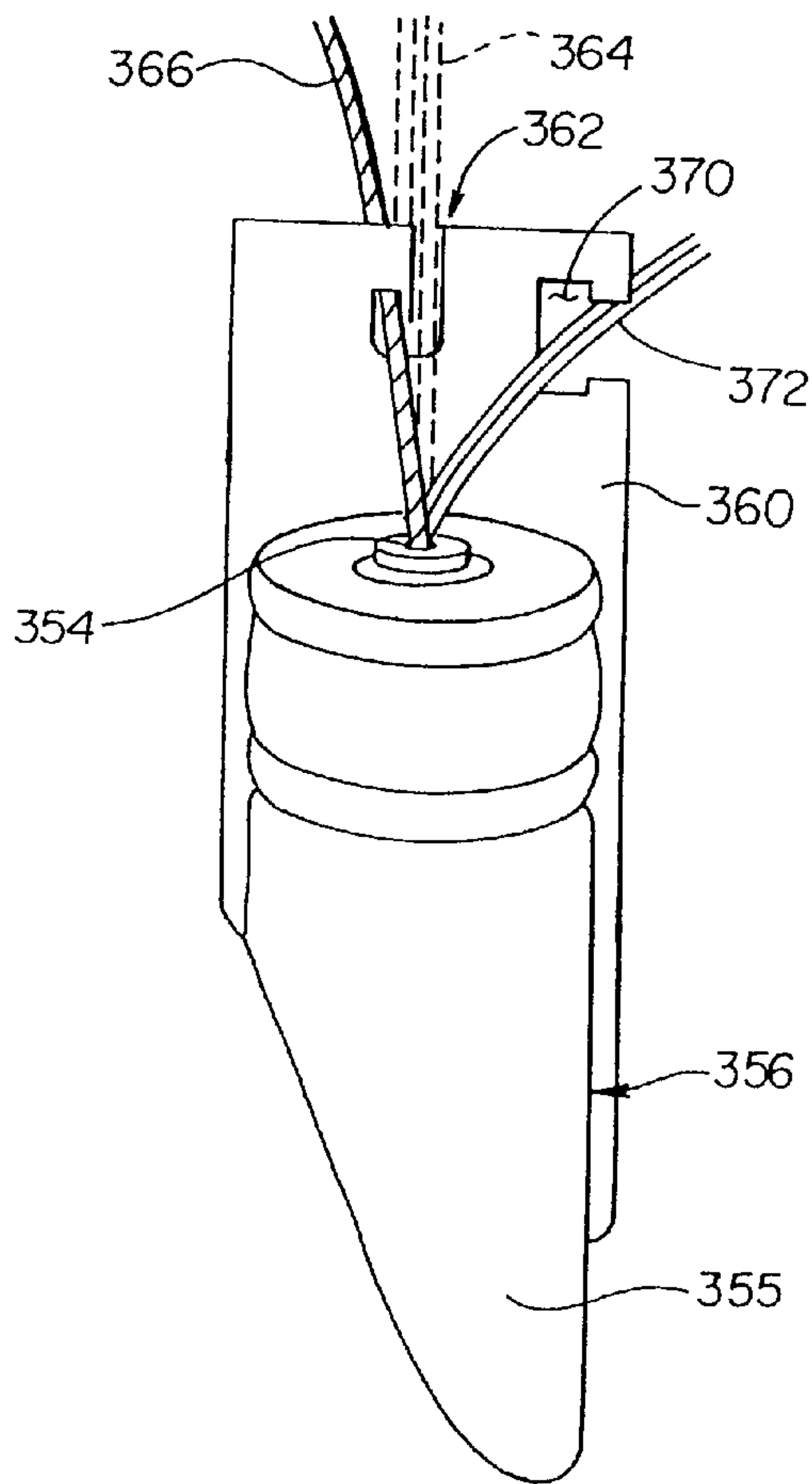


**Fig. 10**

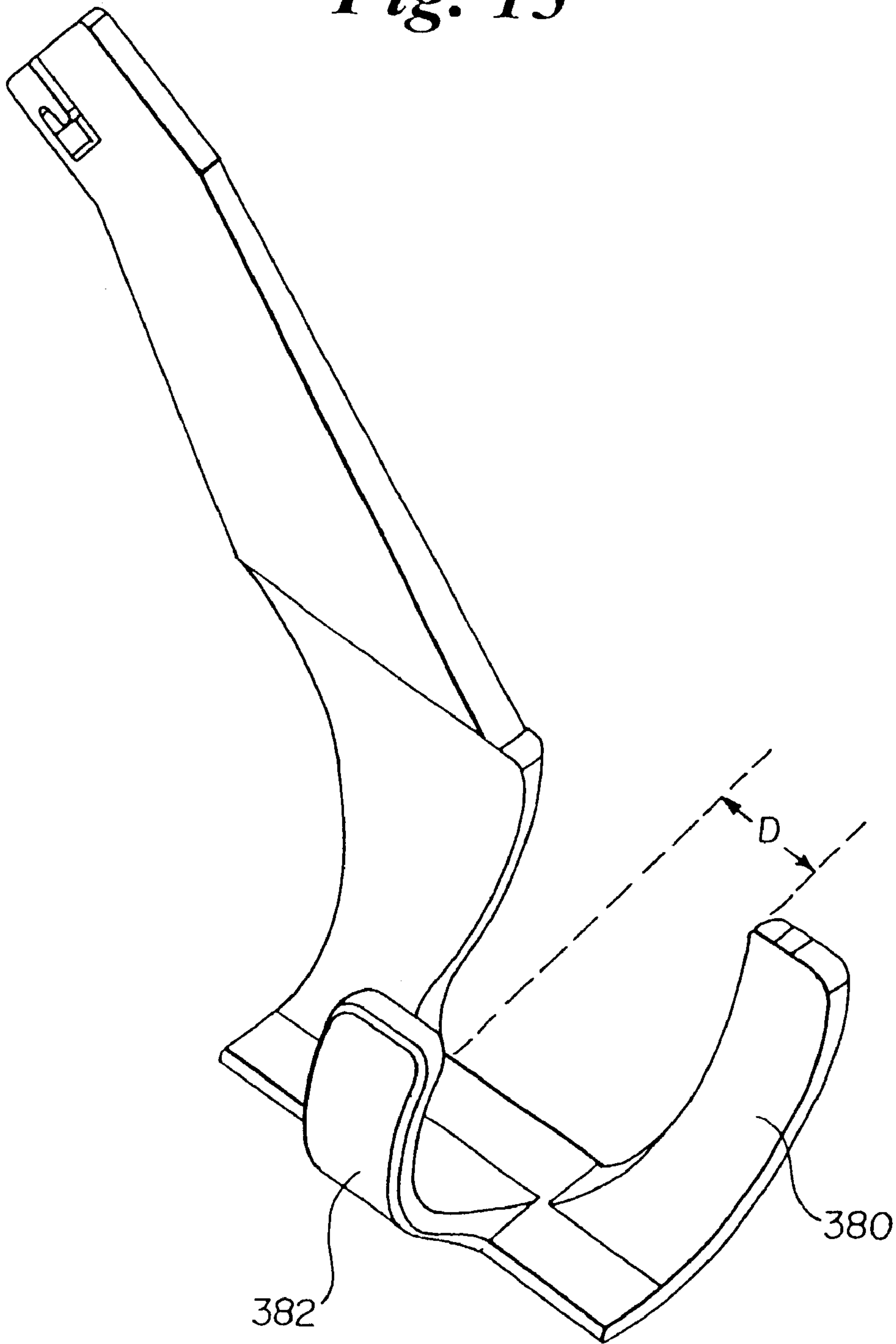
*Fig. 11*



*Fig. 12*

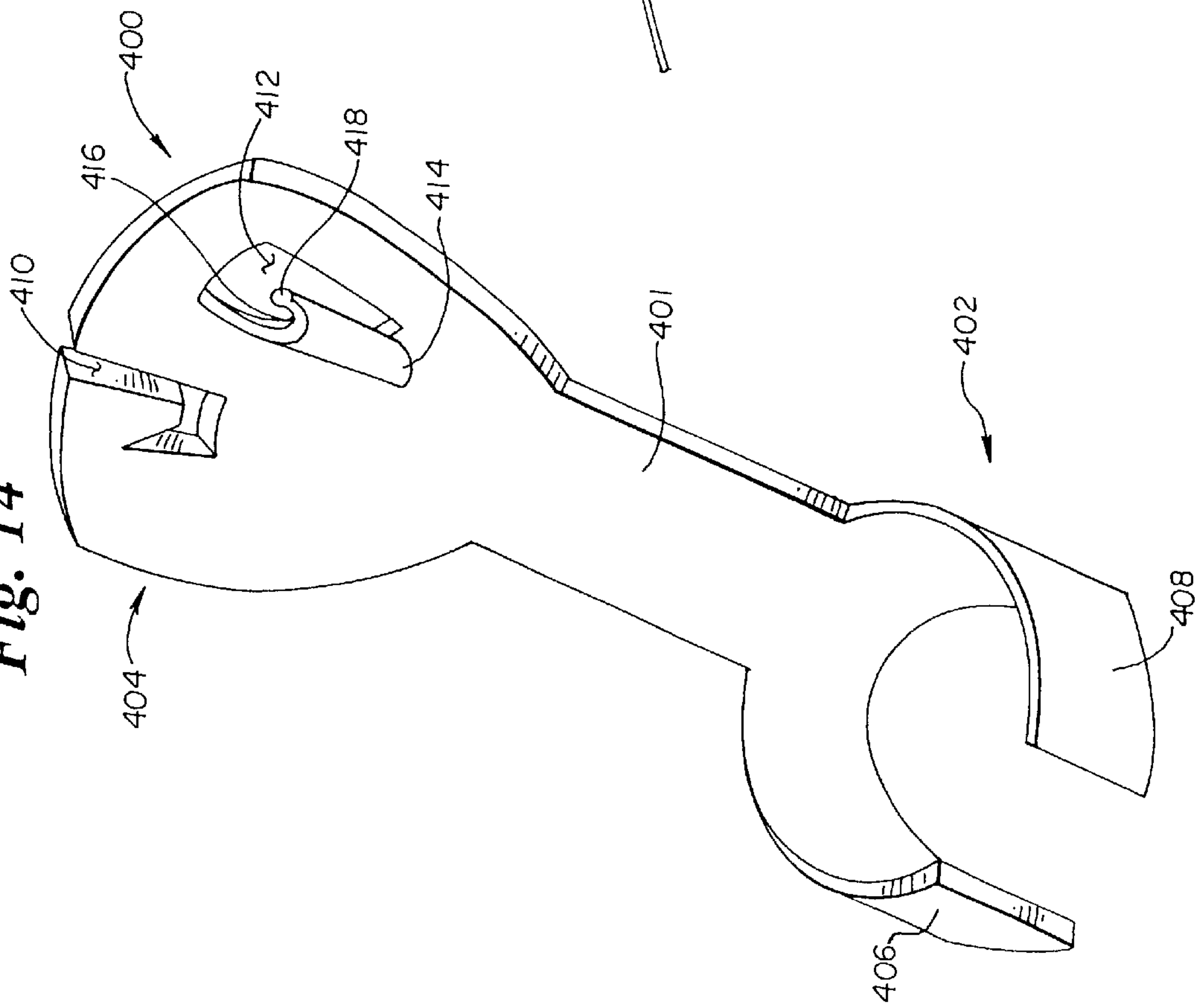


*Fig. 13*

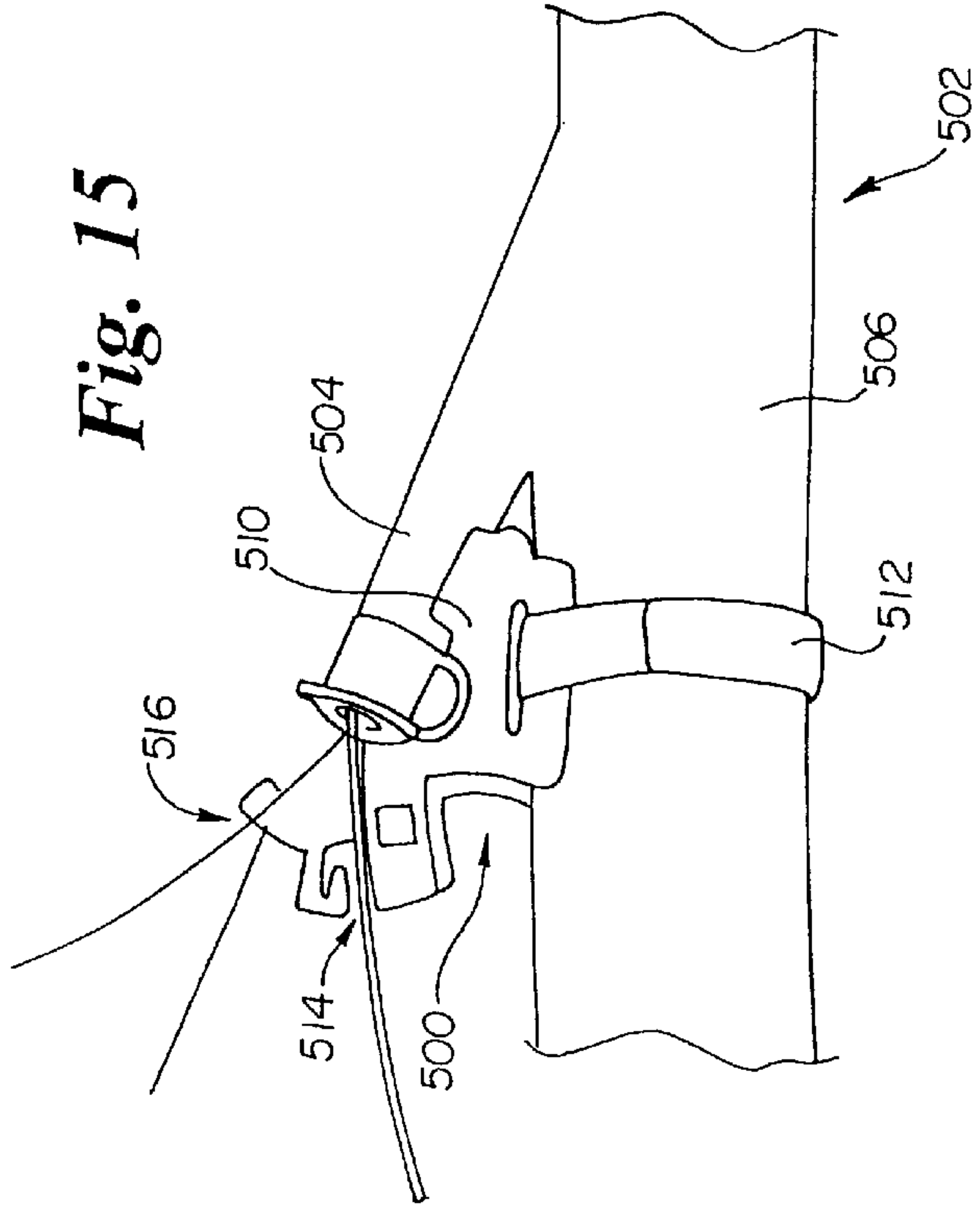




**Fig. 14**



**Fig. 15**



## GUIDEWIRE AND CATHETER LOCKING DEVICE AND METHOD

This application is a continuation of U.S. patent application Ser. No. 09/080,520, filed May 18, 1998, now U.S. Pat. No. 6,096,009, issued Aug. 1, 2000 which is a continuation-in-part application of U.S. patent application Ser. No. 08/926,200, filed on Sep. 9, 1997, entitled "Single Operator Exchange Biliary Catheter", now U.S. Pat. No. 6,007,522, issued Dec. 28, 1999, which claims priority under 35 U.S.C. §119(e) to provisional application U.S. Ser. No. 60/025,235, filed Sep. 13, 1996, entitled "Single Operator Exchange Biliary Catheter".

### FIELD OF THE INVENTION

The present invention relates to a guide wire and/or a catheter locking device for use in catheter procedures within the human anatomy, and methods of using the same. The locking device is particularly useful during catheter exchange procedures. The present invention includes a locking device that is attached to an endoscope, a guide catheter, or other guiding type catheter that receives a guide wire and/or another catheter. The locking device is used to selectively secure the guide wire and/or catheter in a desired position within the endoscope or guiding type catheter. This may reduce the likelihood that the guide wire and/or catheter will move from a desired placement during a procedure, such as a catheter exchange procedure.

### DESCRIPTION OF THE PRIOR ART

Endoscopic procedures for treating abnormal pathologies within the alimentary canal system and biliary tree (including the biliary, hepatic, and pancreatic ducts) are increasing in number. The endoscope provides access to the general area of a desired duct using direct visualization. However, the duct itself must be navigated using a catheter in conjunction with fluoroscopy and guide wires. Catheters are known for treatment of targeted anatomical regions. Known methods and devices for using biliary catheters for accessing the biliary tree for performing catheter procedures are disclosed in Weaver et al., U.S. Pat. No. 5,397,302 and Karpel, U.S. Pat. No. 5,320,602, the disclosures of which are herein incorporated by reference. In general, for treatment of an abnormal pathology within a patient's biliary tree, an endoscope is first introduced into the mouth of the patient. The endoscope includes a proximal end and a distal end, and has a lumen extending longitudinally between the proximal and distal ends. The endoscope is guided through the patient's alimentary tract or canal until an opening at the distal end of the endoscope is proximate the area to receive treatment. At this point, the endoscope allows other components, such as a catheter, to access the targeted area. For visualization or treatment within the biliary tree, the distal end of the endoscope is positioned proximate the papilla of Vater leading to the common bile duct and the pancreatic duct. A catheter is guided through the lumen of the endoscope until a distal tip of the catheter emerges from the opening at the distal end of the endoscope.

The catheter may be used for accessing the biliary tree. The distal end of the catheter is guided through the orifice to the papilla of Vater (located between the sphincter of Oddi) leading to the common bile duct and the pancreatic duct. A guide wire may be used in conjunction with the catheter to facilitate accessing a desired location within the biliary tree. The guide wire is inserted in an opening at a proximal end of the catheter and guided through the catheter until it emerges from the distal end of the catheter.

If visualization of the common bile duct is desired, the guide wire is guided into the common bile duct. The catheter is advanced over the guide wire, as previously described, until the distal end of the catheter is positioned in the common bile duct at the desired location. The catheter is now in position for delivery of contrast media for fluoroscopic visualization of anatomical detail within the common bile duct. Visualization may reveal selected areas within the common bile duct that require treatment. To treat the selected areas, a different catheter is typically required, necessitating a catheter exchange. A catheter exchange typically involves removing the first catheter from the endoscope over the guide wire, and advancing a second catheter over the guide wire to the desired treatment site. Thus, once the guide wire is in place relative to the targeted area, it is highly desirable to maintain the position of the guide wire during subsequent catheter procedures, including during a catheter exchange procedure. If the guide wire moves during such a procedure, the guide wire may have to be re-directed through the body ducts to the target site, which is often a difficult, time consuming and tedious task.

In addition to performing a catheter exchange procedure, it may also be desirable to perform a guide wire exchange procedure. This may be desirable when, for example, a first guide wire is too large to fit through a desired body duct, or otherwise lacks the desired characteristics. Under these circumstances, a physician may leave the catheter in place, withdraw the first guide wire from the catheter, and insert a second guide wire through the catheter to the desired site. During this procedure, the catheter guides the guide wire to the desired site. Thus, once the catheter is positioned at a target site, it is highly desirable to maintain the position of the catheter during a guide wire exchange procedure so that the second guide wire may be guided directly to the desired site in a minimum amount of time.

To maintain the position of a guide wire and/or catheter, a physician typically must grasp the proximal end of the guide wire and/or catheter with one hand, and performing the corresponding exchange with the other. This is difficult, and often results in the movement of the guide wire and/or catheter. Therefore, it would be desirable to provide a locking device whereby the physician can secure the position of the guide wire and/or catheter during an exchange procedure, thereby freeing both hands to perform other tasks.

### SUMMARY OF THE INVENTION

The present invention overcomes many of the disadvantages of the prior art by providing a locking device that is mounted on an endoscope or the like for selectively securing the position of a guide wire and/or catheter relative to the endoscope or the like. The locking device preferably includes a side wall with an opening therein for receiving the guide wire or catheter near its proximal end or at any point along the guide wire or catheter's length depending upon how far it is inserted. The opening is preferably J-shaped or boot shaped, and has an entry slot and a locking slot. Once a guide wire or catheter is in a desired position within a body cavity, a portion of the guide wire or catheter that extends outside of the endoscope or the like is aligned with the opening and may be moved into the opening in use. More particularly, a portion of the guide wire or catheter may be inserted by an operator through the entry slot of the opening and into the locking slot, wherein the locking slot frictionally secures the position of the guide wire or catheter relative to the endoscope or the like.

In one illustrative embodiment, the locking device includes a body member that is funnel shaped including a



horn and a neck with a lumen extending therethrough. The horn has a side wall with an opening provided therein. The neck is operatively attached to the endoscope or the like proximate an access port. In this configuration, a proximal portion of the guide wire or catheter extends out of the access port of the endoscope or the like and through the lumen of the locking device. Once a guide wire or catheter is in a desired position within a body cavity, the proximal portion of the guide wire or catheter may be moved into the opening in the body member of the locking device, and frictionally fit therein.

In another illustrative embodiment, the locking device is adapted for use with an endoscope having a side port. The side port is in fluid communication with one or more lumens, and may receive a guide wire or catheter therein. In this embodiment, the locking device includes a body member, an attachment mechanism and a securing mechanism. The attachment mechanism preferably includes one or more hook members that engage the main shaft of the endoscope near the side port. These hook members tend to clip or secure the locking device to the main shaft of the endoscope. The body member extends from the hook members generally parallel to the side port. The securing mechanism, which is preferably an opening in the body member, is preferably positioned near the end of the body member and proximate the side port opening of the endoscope. Once a guide wire or catheter is in a desired position within a body cavity, the proximal portion of the guide wire or catheter, which extends outside of the side port of the endoscope, may be moved into the opening of the locking device and frictionally fit therein. In preferred embodiments, the opening includes an entry slot and a locking slot, as described above.

It is contemplated that the locking device may include more than one securing mechanism for securing more than one guide wire or catheter or combination of guide wires and catheters. This is preferably accomplished by including two or more openings in the body member of the locking device. For example, one opening may be substantially J-shaped for securing a guide wire. Another opening may be boot shaped for securing a catheter. The boot shape is similar to the J-shape but has increased dimensions for receiving the larger catheter shaft.

In use, a guide wire or catheter may be inserted into the lumen of an endoscope or the like. The locking device, which is preferably operatively attached to the shaft of the endoscope or the like, has a wall with an opening therein. The opening is preferably positioned proximate an access port of the endoscope or the like. As described above, the opening preferably has a locking slot that has a reduced dimension relative to the outside portion of the guide wire or catheter. Once the guide wire or catheter is in a desired position within a body cavity, the proximal portion of the guide wire or catheter is selectively secured to the locking device by positioning the guide wire or catheter in the locking slot of the opening.

It is contemplated that the locking device may be used in conjunction with any catheter that receives another device such as a guide wire or another catheter. For example, it is contemplated that the locking device may be used in conjunction with endoscopes, guide catheters, angioplasty catheters, etc. It is also recognized that when securing a guide wire during a catheter exchange procedure, the first and second catheters should be rapid-exchange type catheters to allow access to the guide wire proximate the access port during at least most of the catheter exchange procedure.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be further described with reference to the accompanying drawings, wherein like numbers refer to like parts in several views and wherein:

FIG. 1 is a perspective view of a catheter in accordance with the present invention having a U-shaped channel and guide wire lumen for directing a guide wire along its shaft and for facilitating rapid catheter exchange;

FIG. 1A is a cross-sectional view of the catheter of FIG. 1 taken along the line 1A—1A;

FIG. 1B is a cross-sectional view of the catheter with guide wire of FIG. 1 taken along the line 1B—1B;

FIG. 1C is an enlarged fragmentary perspective view of the encircled catheter section of FIG. 1 at 1C;

FIGS. 2A—2D are cross-sectional views of the catheter of FIG. 1 located within increasingly larger endoscope channels;

FIG. 3 is a perspective view of an endoscope exchange sheath assembly, without slit, suitable for receiving the catheter of FIG. 1;

FIG. 3A is an enlarged fragmentary perspective view of the encircled sheath section of FIG. 3 at 3A;

FIG. 4 is a perspective view of an alternative embodiment sheath assembly having a slit sheath and two-piece hub, shown in an unlocked position;

FIG. 4A is a perspective view of the two-piece hub of FIG. 4 in a locked position;

FIG. 4B is an enlarged fragmentary perspective view of the encircled sheath section of FIG. 4 at 4B, having a slit;

FIG. 4C is an enlarged fragmentary perspective view of a sheath section, having an overlap, an alternate embodiment of the sheath in FIG. 4B;

FIG. 5 is a perspective view of the catheter of FIG. 1 inserted through the endoscope sheath assembly of FIG. 4;

FIG. 6 is a perspective view of a endoscope sheath section containing a catheter having a U-shaped channel containing a guide wire;

FIG. 7 is a partial perspective view of a guide wire within the catheter of FIG. 1 inserted through the endoscope sheath assembly of FIG. 4, which is in turn within an endoscope;

FIG. 7A is a perspective view of the sheath assembly of FIG. 7, having the catheter removed;

FIG. 8 is a partial perspective view of an alternative embodiment of a sheath assembly, including an introducer;

FIG. 8A is an enlarged perspective view of the introducer of FIG. 8;

FIG. 9A is an enlarged, cross-sectional view of an alternative embodiment of the introducer of FIG. 8;

FIG. 9B is an enlarged, cross-sectional view of another alternative embodiment of the introducer of FIG. 8;

FIG. 9C is an enlarged, cross-sectional view of another alternative embodiment of the introducer of FIG. 8;

FIG. 9D is an enlarged, cross-sectional view of another alternative embodiment of the introducer of FIG. 8;

FIG. 9E is an enlarged, perspective view of another alternative embodiment of the introducer of FIG. 8;

FIG. 9F is an enlarged, cross-sectional view of another alternative embodiment of the introducer of FIG. 8;

FIG. 10 is a perspective view of an illustrative locking device;

FIG. 11 is a partial side view of an illustrative locking device positioned on an endoscope having an angled side port;

FIG. 12 is a partial side view detailing the illustrative locking device of FIG. 11;

FIG. 13 is a perspective view of another illustrative locking device;



FIG. 14 is a perspective view of yet another illustrative locking device; and

FIG. 15 is a partial side view of another illustrative locking device positioned on an endoscope having an angled side port.

#### DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows a perspective view of a catheter assembly 30 in accordance with the present invention. Catheter assembly 30 is used in catheter procedures for accessing targeted anatomical regions through the alimentary canal. The present invention incorporates features which allow rapid exchange of a catheter by a single operator. The catheter of the present invention allows shorter length guide wires to be used, resulting in procedures which require less medical personnel, are less time consuming, and less costly. Additionally, the present invention is adaptable to most catheter devices used for catheter procedures within the alimentary canal.

Catheter assembly 30 includes a catheter hub assembly 32 and a catheter 34, having a guide wire 36 passing through a portion thereof. Catheter 34 includes a shaft 38, which in general terms has a proximal end 40, a U-channel 42, a distal tip region 44, a distal end 46 and various lumens described in greater detail below. Catheter hub assembly 32 is operably connected to proximal end 40 of shaft 38. Catheter hub assembly 32 is preferably configured to couple to ancillary devices allowing access to a lumen within shaft 38.

Shaft 38 is a generally tubular shaped member having a generally uniform outer shape at proximal end 40. Shaft 38 may be sized for slidably passage through the lumen of an endoscope (not shown). Shaft 38 is preferably formed in an extrusion process. Shaft 38 may be formed of an extruded polymeric material. In one embodiment, the preferred polymeric material is polytetrafluoroethylene, polyether block amide, nylon or a combination or blend of these. Catheters which are contemplated include, but are not limited to, cannulas, sphincterotomes, cytology devices, and devices for stone retrieval and stent placement.

In a preferred embodiment, shaft 38 further includes a distal taper 48 which tapers to distal tip region 44. Additionally, tip region 44 may include high contrast, color coded distal markers 50. Finally, distal end 46 may be radiopaque for fluoroscopic visualization of distal tip region 44 during a catheter procedure.

U-channel 42 of shaft 38 extends between a first, proximal channel end 52 and a second, distal channel end 54. U-channel 42 serves to contain, but not necessarily constrain, guide wire 36, between channel proximal end 52 and channel distal end 54. The term "U-channel" refers to a channel shape that allows radial removal of guide wire 36 from the channel 42, and need not be strictly in the shape of the letter U. Channel 42 in the preferred embodiment is sufficiently large to allow unhindered radial guide wire 36 movement out of channel 42. Further, the channel walls and radial opening are substantially equal to or slightly larger than the diameter of a guide wire lumen, described in greater detail below. Although it is recognized that proximal channel end 52 may be located at any location distal of proximal end 40 of shaft 38, channel distal end 54 is preferably located between 10 and 40 cm from distal end 46 of catheter shaft 38.

Finally, as shown in FIG. 1A, which is a cross-sectional view of shaft 38 taken along line 1A—1A at a location proximal of channel proximal end 52, shaft 38 includes ancillary lumen 56, ancillary lumen 58 and guide wire lumen 60.

Ancillary lumen 56 and ancillary lumen 58 extend longitudinally between proximal end 40 and distal end 46 of shaft 38. Ancillary lumen 56 and ancillary lumen 58 may be injection lumens, allowing for high contrast media flow capability for bubble-free opacification and for excellent visualization of a desired anatomical region. Additionally or alternatively, ancillary lumen 56 and/or ancillary lumen 58 may be used for or as part of other ancillary devices, such as a cutting wire lumen or a retrieval balloon lumen.

Guide wire lumen 60 extends longitudinally between proximal end 40 and distal end 46 of shaft 38 in the preferred embodiment. Further, guide wire lumen 60 is sized to receive guide wire 36. Guide wire lumen 60 may be a tubular member which is extruded integral catheter shaft 38, or alternatively, guide wire lumen 60 may be a separate tubular member which is coupled to catheter shaft 38. Although in one preferred embodiment the guide wire lumen 60 is a tubular member which is located proximate distal end 46 of catheter shaft 38, it is recognized that guide wire lumen 60 may be formed anywhere along shaft 38, may be an extension of shaft 38 coupled to distal end 46, or guide wire lumen 60 may run the entire length of shaft 38.

Referring to FIG. 1B, a cross-sectional view of shaft 38 taken along line 1B—1B of FIG. 1 is shown. Guide wire 36 may access guide wire lumen 60 at a point proximal channel distal end 54. Guide wire 36 extends within channel 42 to channel distal end 54, continuing within guide wire lumen 60 through distal tip region 44, and exiting through an opening in distal end 46.

Referring to FIG. 1C, a section of catheter shaft 38 having U-channel 42 is shown. The embodiment shown also includes ancillary lumens 56 and 58. Sections of shaft 38 proximate the channel proximal end 52 and distal channel distal end 54 contain guide wire lumen 60 in communication with U-channel 42. In one embodiment, U-channel 42 has an interior, closed-side geometry, substantially the same as the geometry of guide wire lumen 60. Further, U-channel 42 walls are spaced further than a diameter of guide wire 36 such that guide wire 36 moves freely into and out of U-channel 42.

Catheter shaft 38 can be configured such that U-channel 42 is defined separately from guide wire lumen 60. With this approach, guide wire lumen 60 is divided into two sections; a first section extending between proximal end 40 of shaft 38 and channel proximal end 52; and a second portion extending between channel distal end 54 and distal end 46 of shaft 38. Alternatively, the shaft can be configured to define guide wire lumen 60 as extending longitudinally between proximal end 40 and distal end 46 of shaft 38. In the alternative embodiment, between channel proximal end 52 and channel distal end 54, guide wire lumen 60 is integral with U-channel 42. In other words, guide wire lumen 60 defines a portion of U-channel 42 such that spacing between outer walls of U-channel 42 is equal to a diameter of guide wire lumen 60. Regardless of how guide wire lumen 60 and U-channel 42 are defined, U-channel 42 provides for access to guide wire lumen 60 at channel distal end 54. In this regard, channel distal end 54 can be enlarged to more easily direct guide wire 36 into guide wire lumen 60.

Guide wire lumen 60 and U-channel 42 allow rapid exchange of catheter assembly 30 when an alternative catheter is necessary during a certain medical procedure. Shorter length guide wires may be used since guide wire 36 does not pass through shaft proximal end 40 and hub assembly 32, but rather exits the catheter shaft 38 at U-channel 42 located substantially distal from proximal end



40. The unique catheter construction in accordance with the present invention will reduce catheter therapeutic and diagnostic procedure time since catheter device exchanges may be performed relatively more easily and quickly by a single operator. Additional personnel and time associated with maintaining the placement of a conventional (approximately 400 cm) guide wire within the targeted anatomical region is eliminated, reducing the overall costs of the procedure.

Referring to FIGS. 2A through 2D, cross-sectional views of endoscope working channels 70–76 containing a catheter according to FIG. 1 are shown. In the examples illustrated in FIGS. 2A through 2D, working channel inside diameters 70, 72, 74, and 76 are 2.8, 3.2, 3.8, and 4.2 mm, respectively. FIG. 2A illustrates catheter shaft 38 having ancillary lumens 54 and 56, U-channel 42, and guide wire 36 within U-channel 42. Further, shaft 38 is shown within a first size endoscope working channel 70. In FIG. 2A, guide wire 36 is effectively radially constrained by small sized working channel 70 that closely surrounds U-channel 42.

FIG. 2B illustrates catheter containment within a second size working channel 72, slightly larger than the working channel 70 of FIG. 2A. In FIG. 2B, guide wire 36 is able to move out of U-channel 42 to a position denoted with dashed lines at 80. FIG. 2C shows shaft 38 contained within a third, even larger sized working channel 74. Guide wire 36 is able to move completely out of U-channel 42 to position 82 shown with dashed lines. Finally, FIG. 2D demonstrates catheter shaft 38 within a fourth size working channel 76. In this even larger working channel, guide wire 36 lies within an even larger cross-sectional area, and is able to move to a position shown in FIG. 2D with dashed lines at 84.

As shown with the larger endoscope working channels (FIGS. 2C and 2D), the potential for guide wire 36 to slip out of U-channel 42 creates a potential for the guide wire 36 to become pinched and restrict desired movements of both guide wire 36 and catheter shaft 38. For this reason, when larger endoscope working channels are used, an exchange sheath having a sufficiently small inner diameter so as to constrain guide wire movement to within the catheter U-channel 42 is employed with the preferred embodiment. Generally speaking, an endoscope exchange sheath in accordance with the preferred embodiment allows for use of a radially accessible guide wire, which is longitudinally aligned with the catheter, while presenting a circular profile to an endoscope and mitigating guide wire pinching problems between the catheter and the endoscope working channel wall.

Referring to FIG. 3, an endoscope exchange sheath assembly 100 having sheath hub assembly 102 and a sheath 104 is shown. The sheath 104 includes a lumen 106 and a distal end 108. FIG. 3A shows a section of sheath 104, having lumen 106 for receiving a catheter. Basically, with reference to FIG. 1, catheter 34 is fed through lumen 106 of sheath 104 such that sheath 104 encompasses guide wire 36 within U-channel 42. Sheath 104 is adapted to be disposed within an endoscope working channel, thereby providing a smaller diameter channel than that of the surrounding endoscope working channel constraining the guide wire 34 (FIG. 1) to the U-channel 50 (FIG. 1), and mitigating the potential problems shown in FIGS. 2C and 2D.

Referring to FIG. 4, an alternate endoscope exchange sheath assembly 110 is shown. Sheath assembly 110 includes a two-piece hub assembly 112 and a sheath 114 defining lumen 116 and having slit 118 extending longitudinally over its length, terminating at distal end 120. Slit 118 in sheath 114 is shown in more detail in FIG. 4B.

Referring again to FIG. 4, two-piece hub assembly 112 has a proximal hub portion 122 and a distal hub portion 124, having a proximal slit 126 and a distal slit 128, respectively. Sheath slit 118 is in communication with hub slits 126 and 128, allowing a guide wire (not shown) to be radially slid into or out of sheath assembly 110. Proximal hub portion 122 is shown unlocked (position “A”) in FIG. 4, aligning hub proximal slit 126 with hub distal slit 128 and sheath slit 118, providing a continuous slit for guide wire radial movement into and out of the sheath assembly 110. Proximal hub portion 122 is shown locked, in position “B”, in FIG. 4A, whereby proximal hub slit 126 is rotated with respect to distal hub slit 128, preventing a guide wire (not shown) within hub assembly 112 from being moved radially out of hub assembly 112. Proximal hub portion 122 is set to position B (FIG. 4A) when radial guide wire movement is not desired.

FIG. 4C illustrates a portion of an alternate embodiment sheath 130 having a lumen 132, a sheath wall opening 134 and sheath wall overlap 136. A guide wire (not shown) is able to be slid out of lumen 132 of sheath 130 by maneuvering the guide wire into sheath wall opening 134 and through overlap 136.

Referring to FIG. 5, catheter assembly 30 depicted in FIG. 1 is shown inserted within endoscope exchange sheath assembly 110 depicted in FIG. 4. More particularly, catheter 34 is inserted through slitted sheath assembly 110, extending distally out sheath distal end 120. Guide wire 36 (shown partially in FIG. 5) is positioned within U-channel 42 of catheter 34, along guide wire lumen 60 (FIG. 1B), and extends from shaft distal end 46. Further, guide wire 36 is engaged by hub assembly 112. More particularly, guide wire 36 passes within and is engaged by proximal slit 126 and distal slit 128 of hub assembly 112. Sheath proximal hub portion 122, having proximal slit 126, is shown in locked position relative to sheath distal hub portion 124, having distal slit 128. Thus, in the locked position, hub assembly 112 of sheath assembly 110 prevents radial withdrawal of guide wire 36, otherwise inserted in U-channel 42 of catheter 34, from distal the channel proximal end 52.

Referring to FIG. 6, a section of FIG. 5 is shown in detail, having endoscope sheath 114 containing catheter shaft 38, which further maintains guide wire 36 within U-channel 42. As shown, sheath 114 is able to constrain movement of guide wire 36 from U-channel channel 42 when sheath 114 is within a larger endoscope working channel, for example as illustrated in FIGS. 2C and 2D. Importantly, the sheath 114 embodiment illustrated in FIG. 6 includes longitudinal slit 118, allowing guide wire 36 to be peeled from catheter shaft 38 and endoscope sheath 114. In other words, as previously described, U-channel 42 is sized larger than guide wire 36 such that guide wire 36 can displace radially from U-channel 42. Sheath 114 prevents undesired displacement of guide wire 36 from U-channel channel 42 under normal operating conditions. However, if adequate radial force is placed on guide wire 36 by an operator, guide wire 36 will separate sheath 114 along slit 118 such that guide wire 36 is displaced from sheath 114 and U-channel 42. Referring to FIG. 7, guide wire 36 is shown inserted within catheter assembly 30 of FIG. 1, which is inserted through endoscope sheath assembly 110 of FIG. 4, which is in turn within an endoscope 150. Sheath assembly 110 includes sheath 114 that has slit 118 and two-piece hub assembly 112, shown at a locked position “B” (also in FIG. 4A). Having hub assembly 112 locked prevents guide wire 36 from moving radially out of sheath 114 through slit 118. Guide wire 36 can be restrained from longitudinal movement by applying finger pressure on the guide wire 36 against hub assembly 112.



Referring to FIG. 7A, endoscope **150** and sheath assembly **110** of FIG. 7 are shown without the catheter assembly **30** inserted, as after catheter withdrawal. Sheath hub assembly **112** is shown in unlocked position at "A" (also in FIG. 4). Having hub assembly **112** unlocked allows radial movement of guide wire **36** out of sheath **114** through slit **118**, but such movement may be restrained by trapping guide wire **36** against the outside of sheath **114** using one finger, providing ease of guide wire **36** control during catheter exchanges.

In one possible endoscopic procedure, an endoscope **150**, as illustrated in FIG. 7, is first introduced into the mouth of a patient and is guided through the patient's alimentary canal. Specifically, endoscope **150** is guided down the esophagus, through the stomach, past the pyloric sphincter of the stomach and into the duodenum. Endoscope **150** has a lumen extending longitudinally between its proximal end and the distal end. Endoscope **150** is guided through the alimentary canal until a distal end (not shown) of endoscope **150** is proximate the target area within the anatomy to receive treatment. In an endoscopic biliary procedure, endoscope **150** is guided into the duodenum until the opening at the distal end of the endoscope **150** is proximate the papilla of vater. The papilla of vater is located between the sphincter of oddi, which leads to the common bile duct, hepatic, and pancreatic ducts. The proximal end (shown in FIGS. 7 and 7A) of endoscope **150** extends and remains outside the mouth of the patient.

With endoscope **150** properly positioned within the patient, catheter assembly **30** is prepared for insertion into the endoscope. First, guide wire **36** is fed into the guide wire lumen **60** (FIGS. 1A-1C) of shaft **38**. More particularly, a distal end of guide wire **36** is placed within U-channel **42**, distal the channel proximal end **52**. The guide wire **36** is then fed to channel distal end **54** (FIG. 1) into guide wire lumen **60**. Finally, guide wire **36** is fed through shaft **38** to distal tip region **40** (FIG. 1). In one method, catheter **32** is then inserted directly into endoscope **150** working channel. This method may be practiced with an endoscope having a sufficiently small working channel inside diameter, as illustrated in FIG. 2A, to constrain guide wire **36** movement without a sheath.

However, in a preferred method (with reference to FIG. 7), catheter assembly **30**, threaded with guide wire **36**, is inserted into sheath assembly **110**, thereby constraining guide wire **36** from slipping radially out of U-channel **42**. More particularly, catheter **34** is inserted into endoscope **150** working channel, but leaving channel proximal end **52** proximate sheath hub assembly **112**, and leaving a portion of guide wire **36** extending from the channel proximal end **52** as well. Notably, sheath hub assembly **112** includes hub slits **126** and **128** which receive a portion of guide wire **36**. Thus, in the preferred embodiment, hub assembly **112** is locked, preventing unwanted radial guide wire **36** movement. In a preferred method, the loading of guide wire **34** into catheter shaft **38** and catheter shaft **38** into sheath assembly **110** is done prior to inserting endoscope **150** into a patient (not shown).

Endoscope sheath **114**, containing catheter shaft **38**, is inserted into endoscope **150** working channel. Endoscope sheath **114** serves to constrain radial guide wire **36** movement over the approximate length of U-channel **42**. Catheter shaft **38** and sheath **114** are inserted together into endoscope **150** until both are near a distal end (not shown) of endoscope **150**. Catheter shaft **38** and sheath **114** may be, either or both, advanced until exiting the distal end of endoscope **150**.

In one method, guide wire **36** is advanced until guide wire **36** distal tip is positioned within the target area in the biliary

tree (including the common bile, hepatic or pancreatic ducts). For example, the distal tip of guide wire **36** may be guided through the orifice leading to the papilla of vater for access to the biliary tree. Catheter shaft **38** may then be advanced over guide wire **36**, tracking catheter assembly **30**, until catheter distal tip region **40** (FIG. 1) exits distal end of endoscope **150** and is positioned within the desired duct. In another method, guide wire **36** and catheter assembly **30** are advanced together until catheter distal end **42** (FIG. 1) is positioned at the target area. It is also recognized that the catheter could be first advanced to near the target area, followed by inserting the guide wire when needed to advance the catheter further.

Once guide wire **36** is in position at the target area, catheter procedures, including injecting contrast media, such as radiopaque dye, through ancillary lumens **56** or **58** (FIGS. 1A-1C) into the common bile duct for visualization of the duct, can be performed. After the desired catheter procedure has been completed, catheter assembly **30** can be exchanged or removed from endoscope **150**, leaving guide wire **36** in position for other catheter procedures. Catheter assembly **30** and sheath assembly **110** may also be removed together.

One method of withdrawing catheter **34** from endoscope **150** is possible using either a slitted/overlapped endoscope sheath **114** as depicted in FIGS. 4 through 4C, or a sheath **104** without a slit as depicted in FIGS. 3 through 3A. Using this method, best visualized with reference to FIG. 7, guide wire **36** is held to prevent longitudinal movement while catheter **34** is retracted within endoscope sheath **114** (or **104**). Catheter **34** retraction leaving the guide wire **36** in position within the patient is enabled by U-channel channel **42** being radially open to guide wire **36** removal in catheter shaft **36**. Once catheter retraction has brought channel distal end **54** (FIG. 1) to a point proximate sheath hub assembly **112**, only a relatively short portion of guide wire **36**, from channel distal end **54** to distal end **46** (FIG. 1) of catheter shaft **38**, remains within catheter **34**. A single operator can remove this remaining portion of guide wire **36** from catheter **34** by first slightly retracting catheter assembly **30** (while still holding guide wire **34** in place) out of sheath assembly **110** (or **100**), such that a portion of guide wire **36** is accessible distal of catheter distal end **46**. In other words, a small portion of guide wire **36** is accessible between distal end **46** of catheter **34** and distal hub portion **124** of sheath assembly **110**. The accessible portion of guide wire **36** is then held by the operator, while withdrawing the remaining portion of catheter **34** completely over guide wire **36**. In an alternative method, the distal end of the endoscope can include an elevator which could be utilized to lock the distal end of the guide wire in position while the catheter is removed.

Exchange of endoscope sheath assembly **110** may be desired, as when a stent (not shown) is to be advanced over guide wire **36**, and the stent has a larger outside diameter than can be accommodated by the sheath **114**. One method of exchanging an endoscope sheath assembly **110** may be used where sheath **114** is slitted as in FIG. 4B, or overlapped, as in sheath **130** in FIG. 4C. Referring to FIG. 7A, two-piece hub assembly **112** is turned to the unlocked position "A" (also shown in FIG. 4). Guide wire **36** is pulled radially away from sheath hub assembly **112** and through slit **118** in sheath **114**. Guide wire **36** is then held, preferably against some portion of endoscope **150**, to prevent guide wire **36** from being dislodged from position within the patient. Sheath **114** is retracted from endoscope **150**, guide wire **36** being "peeled" away from sheath **114**. Sheath retraction is continued until sheath **114** is completely outside of endo-



scope **150** and over guide wire **36**. At this point, guide wire **36** is within endoscope **150** working channel, and stents, catheters, and endoscope sheaths may be advanced over guide wire **36**.

Another method of exchanging both endoscope sheath assembly **110** and catheter assembly **30** may be used where the sheath **114** is slitted as in FIG. 4B, or overlapped, as in sheath **130** in FIG. 4C. Referring to FIGS. 7 and 7A, two-piece hub assembly **112** is turned to the unlocked position "A" (FIG. 7A). Guide wire **36** is pulled radially away from U-channel **42** of catheter **34**, from hub assembly **112** and through slit **118** in sheath **114**. Guide wire **36** is then held, preferably against some portion of endoscope **150**, to prevent guide wire **36** from being dislodged from position within the patient. Sheath **114** and catheter **34** are retracted from endoscope **150**, with guide wire **36** being "peeled" away from sheath **114**. Sheath assembly **110** and catheter assembly **30** retraction are continued until sheath **114** and catheter **34** are completely outside of endoscope **150** and over guide wire **36**. At this point, guide wire **36** remains in a position within endoscope **150** and patient. A single operator can access a small portion of guide wire **36** between distal end **46** (FIG. 1) of catheter **34** to hold guide wire **36** in place while catheter assembly **30** is completely removed or disengaged from guide wire **36**.

While sheath assembly **110** has been described as including a two-piece hub assembly **112** in conjunction with sheath **114**, other assemblies may be used. For example, referring to FIG. 8, an alternate sheath assembly **160** is shown. Sheath assembly **160** includes an introducer **162**, an attachment means **164** and a sheath **166**. Similar to previous embodiments, sheath **166** defines a lumen (not shown) and includes a slit **168** extending longitudinally over its length, terminating at a distal end **170**. Sheath **166** is generally identical to sheath **104** and sheath **114** previously described. Introducer **162** is attached to sheath **166** by attachment means **164** such that lumen (not shown) of sheath **166** is in fluid communication with an interior portion of introducer **162**. In one preferred embodiment, attachment means **164** is a flexible membrane which seals sheath **166** to introducer **162**. Alternatively, other forms of attachment, such as an adhesive or frictional engagement between introducer **162** and sheath **166** may also be useful.

Referring to FIG. 8A, introducer **162** is shown in greater detail. Introducer **162** is a funnel-shaped device including a horn **172** and a neck **174**. In one preferred embodiment, horn **172** and neck **174** are integrally formed as a singular body.

Horn **172** is preferably a conically-shaped body having an outer wall **176**. Outer wall **176** defines an interior space and includes a guide wire-receiving notch **180** formed near proximal end **182** of horn **172**. Guide wire-receiving notch **180** is preferably J-shaped and includes an entry end **184** and a locking end **186**. As shown in FIG. 8A, entry end **184** is open at proximal end **182** of horn **172**. Conversely, locking end **186** is closed.

Neck **174** is preferably tubular in shape, and includes a passage **188**. Passage **188** is configured to be in fluid communication with interior space of horn **172**. In the preferred embodiment, horn **172** and neck **174** are formed of a plastic material. Alternatively, any other semi-rigid or rigid, surgically-safe material may be used.

Referring to FIGS. 1, 8 and 8A, during use, catheter assembly **34** (FIG. 1) is inserted within sheath assembly **160**. More particularly, distal end **46** (FIG. 1) of catheter shaft **38** (FIG. 1), including guide wire **36** (FIG. 1) is placed within horn **172** of introducer **162**. The conical shape of horn **172**

assists in directing distal end **46** of catheter shaft **38**, including guide wire **36**, into passage **188** of neck **174**. Catheter shaft **38** continues forward within lumen (not shown) of sheath **166** until distal end **46** of catheter shaft **38** extends from distal end **170** of sheath **166**.

Once properly inserted within sheath assembly **160**, a proximal end of guide wire **36** (FIG. 1) is maintained within guide wire-receiving notch **180**. More particularly, a portion of guide wire **36** is forced by an operator through entry end **184** of guide wire-receiving notch **180** and forced within locking end **186** thereof. In this regard, locking end **186** preferably has a diameter slightly smaller than that of guide wire **36**. Thus, locking end **186** frictionally maintains guide wire **36**. Conversely, guide wire **36** can easily be released from guide wire-receiving notch **180** by sliding guide wire **36** from locking end **186** and out of entry end **184**. Thus, sheath assembly **160** functions in a manner highly similar to sheath assembly **100** and sheath assembly **110** previously described.

Referring to FIG. 9A, an alternative embodiment of an introducer **190** is shown. Introducer **190** includes a horn **192**, a neck **194** and a valve **196**. Similar to previous embodiment, horn **192** and neck **194** are preferably integrally formed as a singular body. Horn **192** includes an outer wall **197** which defines a guide wire-receiving notch **198** and valve-receiving slots **200**. Valve **196** includes a valve body **202** sized to fit within outer wall **197** of horn **192**. Further, valve **196** includes ribs **204** extending from valve body **202**. Ribs **204** are preferably sized to mate within valve-receiving slots **200** of horn **192**. Thus, valve **196** is maintained within horn **192** via interaction of ribs **204** with valve-receiving slots **200**. In this regard, valve-receiving slots **200** are preferably positioned along horn **192** proximal neck **194**. Valve **196** is preferably made of a rubber-type material.

During use, introducer **190** functions in a manner highly similar to introducer **162** (FIGS. 8 and 8A) previously described. Additionally, however, valve **196** forms a seal about catheter shaft **38** (FIG. 1). Thus, upon insertion into a human body, valve **196** prevents bodily fluids, such as bile, from backing up through the sheath assembly. Additionally, valve **196** can provide for aspiration, if desired.

Referring to FIG. 9B, an alternative embodiment of an introducer **206** is shown. Introducer **206** is highly similar to introducer **190** (FIG. 9A) previously described. In this regard, introducer **206** includes a horn **208**, a neck **210** and a valve **212**. Horn **208** is preferably integrally formed with neck **210** and includes an outer wall **214** defining a guide wire-receiving notch **216** and valve-receiving slots **218**. Similar to valve **196** (FIG. 9A), valve **212** includes a valve body **220** and ribs **222**. Ribs **222** are sized to mate within valve-receiving slots **218** of horn **208**. In this regard, valve-receiving slots **218** are positioned proximate a proximal end **224** of horn **208**. Introducer **206**, including valve **212**, functions in a manner highly similar to introducer **190** (FIG. 9A) as previously described.

It is recognized that the fluid blocking function provided by valve **212** can be achieved with other designs. For example, referring to FIG. 9C, an alternative embodiment of an introducer **226** is shown. Introducer **226** includes a horn **228**, a neck **230** and an O-ring **232**. Horn **228** and neck **230** are preferably formed as an integral body. Horn **228** preferably includes a guide wire-receiving notch (not shown) similar to that previously described and an interior slot **234**. Interior slot **234** is preferably positioned proximate neck **230** and is sized to maintain O-ring **232**. Alternatively, interior slot **234** can be formed in neck **230**.



O-ring 232 is preferably made of a rubber-type material. Further, O-ring 232 has an inner diameter slightly smaller than that of horn 228 and neck 230. Thus, during use, O-ring 232 forms a seal about catheter shaft 38 (FIG. 1), blocking passage of bodily fluids, such as bile, into horn 228.

Referring to FIG. 9D, another alternative embodiment of an introducer 236 is shown. Introducer 236 is similar to a touhey-borst system and includes an upper horn section 238, a lower horn section 240 and a grommet 242. Upper horn section 238 includes an outer wall 244 defining a proximal end 246, a grommet-receiving flange 248 and a distal end 250. Proximal end 246 of horn section 238 preferably includes a guide wire-receiving notch (not shown) similar to that previously described. Distal end 250 is threaded and includes a passage 252 sized to receive a portion of lower horn section 240.

Lower horn section 240 includes a body 254 defining a proximal end 256, an intermediate portion 258 and a distal end 260. An interior passage 266 is configured to communicate with passage 252 and extends from proximal end 256 to distal end 260. Finally, proximal end 256 includes a threaded slot 262 sized to threadably receive distal end 250 of upper horn section 238.

Grommet 242 is preferably made of a rubber-type material and is sized to nest within grommet-receiving flange 248 of upper horn section 238 while abutting proximal end 256 of lower horn section 240.

Introducer 236 is assembled by placing grommet 242 within grommet-receiving flange 248 of upper horn section 238. Distal end 250 of upper horn section 238 is then threadably secured to proximal end 258 of lower horn section 240. As upper horn section 238 is threadably secured to lower horn section 240, proximal end 256 of lower horn section 240 compresses grommet 242 within grommet-receiving flange 248 of upper horn section 238. During use, introducer 236 functions in a manner highly similar to that previously described. In this regard, grommet 242 forms a seal about catheter shaft 38 (FIG. 1). Further, aspiration can be achieved, if desired, by loosening lower horn section 240 relative to upper horn section 238.

Referring to FIG. 9E, yet another alternative embodiment of an introducer 266 is shown. Introducer 266 includes a horn 268, a neck 270 and a valve 272. Preferably, horn 268, neck 270 and valve 272 are integrally formed as a singular body. In this regard, valve 272 is formed while molding horn 268 and neck 270 by imparting a controlled flash at distal end 274 of neck 270.

Introducer 266 performs in a manner highly similar to that previously described. Thus, valve 272 forms a seal about catheter shaft 38 (FIG. 1), thereby preventing back flow of bodily fluids, such as bile, into horn 268.

Referring to FIG. 9F, another alternative embodiment of an introducer 276 is shown. Introducer 276 includes a horn 278, a neck 280 and a valve 282. Horn 278 and neck 280 are preferably integrally formed as a singular body. In this regard, horn 278 and neck 280 are defined by an outer wall 284. Outer wall 284 forms a guide wire-receiving notch 286 and an exterior slot 288. Guide wire-receiving notch 286 is similar to that previously described. Exterior slot 288 is positioned along neck 280 and is sized to maintain a portion of valve 282. Alternatively, exterior slot 288 can be positioned along horn 278.

Valve 282 is preferably a rubber-type sock defined by an upper rib 290, a side wall 292 and a shoulder 294. Upper rib 290 is preferably sized to mount within exterior slot 288 of neck 280. Side wall 292 is preferably flexible so as to stretch

along neck 280. Finally, shoulder 294 is preferably configured to abut a distal end 298 of neck 280. With this configuration, valve 282 is placed over distal end 298 of neck 280 such that shoulder 294 contacts distal end 298. Due to the preferred flexible characteristic of valve 282, side wall 292 is stretched until upper rib 290 nests within exterior slot 288 of neck 280.

During use, the catheter shaft 38 (FIG. 1) is placed through introducer 276 such that shoulder 294 of valve 282 forms a seal about catheter shaft 38. Thus, valve 282 prevents undesired back flow of bodily fluids, such as bile.

FIG. 10 is a perspective view of an illustrative locking device for use with an endoscope having a side instrument port. The illustrative locking device is generally shown at 320 and includes a body member 322. At one end, the body member 322 includes one or more hook members 324 for attaching the locking device to a shaft of an endoscope or the like (see FIG. 11). At the other end, the body member 322 includes a securing mechanism for securing a guide wire or catheter to the locking device.

The hook members 324 may be provided in pairs, as shown in FIG. 10, or offset from one another, as shown in FIG. 13. In either case, the hook members 324 are adapted to clip and secure the locking device to the shaft of an endoscope or the like.

The securing mechanism preferably includes one or more openings provided in the body member 322. In the embodiment shown, the body member 322 includes a guide wire opening 326 and a catheter opening 332. The guide wire opening 326 is similar to the guide wire-receiving notch 180 of FIG. 8A. The guide wire opening 326 is preferably J-shaped, and preferably includes an entry slot 328 and a locking slot 330. The catheter opening 332 is boot shaped, and also preferably includes an entry slot 334 and a locking slot 336.

The entry slot 328 of the guide wire opening 326 is dimensioned to be larger than the diameter of a guide wire. The locking slot 330 of the guide wire opening 326 is dimensioned to be somewhat smaller than the diameter of a guide wire. Accordingly, a guide wire can be secured to the body member 322 by inserting a portion of the guide wire through the entry slot 328 of the guide wire opening 326 and into the locking slot 330. The locking slot 330 frictionally secures the guide wire relative to the body member 322.

Likewise, the entry slot 334 of the catheter opening 332 is dimensioned to be larger than the diameter of a catheter. The locking slot 336 of the catheter opening 332 is dimensioned to be somewhat smaller than the diameter of a catheter. Accordingly, a catheter can be secured to the body member 322 by inserting a portion of the catheter through the entry end 334 of the catheter opening 332 and into the locking slot 336. The locking slot 336 frictionally secures the catheter relative to the body member 322.

FIG. 11 is a partial side view of an illustrative locking device positioned on an endoscope with an angled side port extending therefrom. The endoscope is generally shown at 350, and includes a main shaft 352 with a lumen extending therethrough. A side port 356 extends laterally away from the main shaft 352 at an angle. The side port 356 provides access to the lumen of the main shaft 352. Accordingly, a guide wire and/or catheter may access the lumen of the main shaft 352 via the side port 356.

The side port 356 preferably includes a side port opening 354 which is laterally spaced from the main shaft 352 due to the angular displacement between the main shaft 352 and the side port 356. The side port opening 354 is in fluid com-



munication with the lumen of the main shaft 352 via a connection tube 355. The connection tube 355 intersects a side wall of the main shaft 352 at an angle, as shown.

A locking device having a body member 360 is shown clipped onto the main shaft 352 of the endoscope. The body member 360 includes a number of hook members 358 for attaching the locking device to the main shaft 352. Two hook members are visible in FIG. 11. The hook members 358 are similar to the hook members 324 described above with respect to FIG. 10.

The body member 360 extends away from the hook members 358 and generally parallel to the side port 356. In FIG. 11, the body member is obscured by the main shaft 352 and side port 356. The body member 360 extends upward past the side port opening 354, wherein a securing mechanism is provided. Preferably, the securing mechanism is a j-shaped guide wire opening 362.

In use, a guide wire is advanced into the body via the endoscope. During the advancement of the guide wire, the proximal end thereof may be moved to a first position 364, which is in the entry slot of the guide wire opening 362. Once the guide wire is in a desired position within the body, the guide wire may be moved to a second position 366, which is in the locking slot of the guide wire opening 362. The locking slot of the guide wire opening 362 frictionally secures the guide wire relative to the body member 360.

FIG. 12 is a partial side view detailing the illustrative locking device of FIG. 11, with an additional oversized catheter opening shown. The side port of the endoscope is shown at 356, and the body member of the locking device is shown at 360. Positioned proximate the side port opening 354 is a guide wire opening 362 and an oversized catheter opening 370. Like above, the guide wire opening is J-shaped and includes an entry slot and a locking slot. Thus, the guide wire may be moved to the first position 364, which is in the entry slot of the guide wire opening 362. Once the guide wire is in a desired position within the body, the guide wire may be moved to the second position 366, which is in the locking slot of the guide wire opening 362. The locking slot of the guide wire opening 362 frictionally secures the guide wire relative to the body member 360.

The oversized catheter opening 370 is sized to restrict lateral movement of the catheter 372 but not longitudinal movement of the catheter 372. Providing a guide wire opening that can secure the guide wire relative to the body member, and an oversized catheter opening for only restricting lateral movement of the catheter 372 may be particularly useful in performing a catheter exchange procedure. For example, during a catheter exchange procedure, the guide wire opening may maintain the position of the guide wire. The oversized catheter opening 370 may separate the catheter from the guide wire, as the catheter is withdrawn. The first and second catheters should be single-operator exchange type catheters to provide access to the guide wire during the exchange.

FIG. 13 is a perspective view of another illustrative locking device. The embodiment shown in FIG. 13 is similar to the embodiment shown in FIG. 10, but the hook members are laterally offset rather than aligned. For example, hook member 380 is laterally offset from hook member 382 by a distance "D". This configuration is another example of an attachment mechanism for attaching the body member to a catheter shaft.

FIG. 14 is a perspective view of yet another illustrative locking device. The locking device is generally shown at 400, and includes a body member 401 having an attachment

mechanism 402 at one end and a securing mechanism 404 at the other. The attachment mechanism 402 includes a first hook member 406 and a second hook member 408. The first hook member 406 and the second hook member 408 are adapted to extend around a substantial portion of the shaft of an endoscope or the like. Thus, the first hook member 406 and the second hook member 408 may clip the body member 401 to the desired shaft.

The securing mechanism 404 includes a J-shaped guide wire opening 410 and a flap-type catheter opening 412. The J-shaped guide wire opening 410 operates similar to that described above. The flap-type catheter opening 412 has a flap 414 formed by cutting the catheter opening 412 from the body member 401. The flap 414 is preferably curved to form a channel 416, wherein the end portion 418 of the channel 416 loops back to near the surface of the body member 401. In this configuration, a catheter or guide wire may be selectively provided in the channel 416, which may bend the flap away from the body member 401. Accordingly, the flap 412 may provide force between the guide wire or catheter and the body member 401 to effectively secured the guide wire or catheter to the body member 401.

FIG. 15 is a partial side view of yet another illustrative locking device 500. The locking device 500 is positioned between the side port 504 and the main shaft 506 of the endoscope 502. The locking device includes a body member 510 that is attached to the main shaft 506 using a strap 512. Preferably, the strap 512 extends around the entire circumference of the main shaft 506. Further, the body member 510 may include a guide wire opening 514 and one or more catheter openings 516, as shown. It will be understood that this disclosure, in many respects, is only illustrative. Changes may be made in details, particularly in matters of shape, size, material, and arrangement of parts without exceeding the scope of the invention. Accordingly, the scope of the invention is as defined in the language of the appended claims.

What is claimed is:

1. A medical system comprising:

an endoscope;

an elongate medical device adapted to be inserted into the endoscope; and

a locking device attached to the endoscope having a locking portion and secured to the elongate medical device to limit relative axial movement between the endoscope and the elongate medical device when the elongate medical device is received in the locking portion and to allow relative axial movement between the endoscope and the elongate medical device when the elongate medical device is out of the locking portion;

wherein the elongate medical device comprises at least one of a catheter and a guide wire.

2. A medical system as in claim 1, wherein the locking device is releasably secured to the elongate medical device.

3. A medical system as in claim 1, wherein the endoscope includes a proximal port and wherein the locking device is attached to the endoscope distal of the proximal port.

4. A medical system as in claim 3, wherein the locking device is secured to the elongate medical device proximal of the proximal port.

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5. A medical system as in claim 4, wherein the elongate medical device comprises a catheter.

6. A medical system as in claim 4, wherein the elongate medical device comprises a guidewire.

7. A medical system as in claim 1, wherein the locking device comprises a body member having a proximal portion and a distal portion, a means for attaching the body member to the endoscope, the attaching means connected to the distal

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portion of the body member, and a means for securing the elongate medical device, the securing means connected to the proximal portion of the body member.

8. The medical system of claim 1, wherein the locking device is releasably attached to the endoscope.

\* \* \* \* \*

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,663,597 B1  
DATED : December 16, 2003  
INVENTOR(S) : Jim Windheuser et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 8,

Line 43, delete "U-channel channel 42", and insert therefor -- U-channel 42 --.

Column 10,

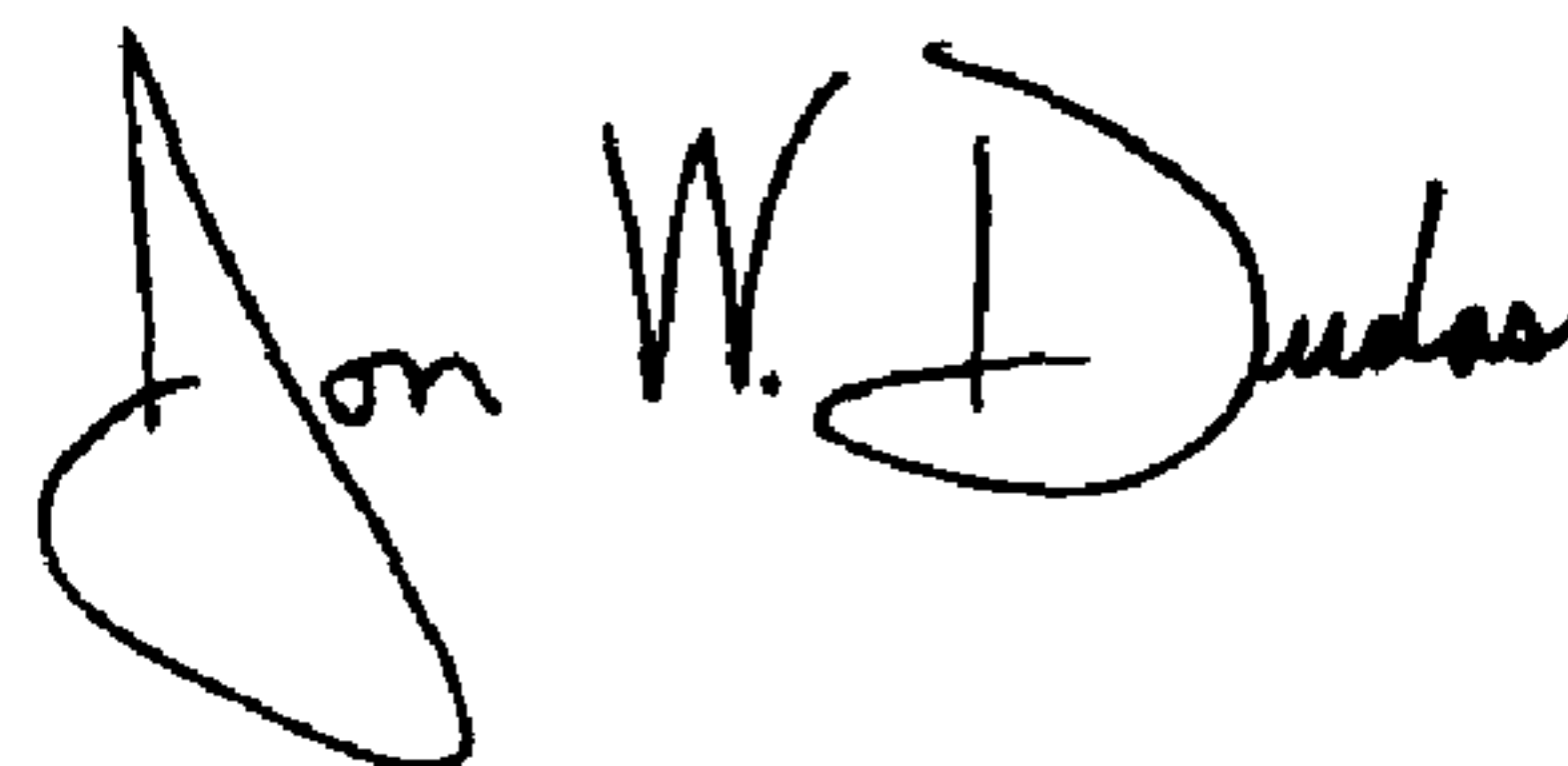
Line 31, delete "U-channel channel", and insert therefor -- U-channel --.

Column 11,

Line 52, delete "J-shaped shaped", and insert therefor -- J-shaped --.

Signed and Sealed this

Sixth Day of July, 2004

A handwritten signature in black ink that reads "Jon W. Dudas". The signature is written in a cursive style with a large, looped initial "J".

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JON W. DUDAS  
*Acting Director of the United States Patent and Trademark Office*